EXHIBIT 6

Uwe Klinge

Experimental investigations with alloplastic materials: Which properties are essential for use at the pelvic floor?

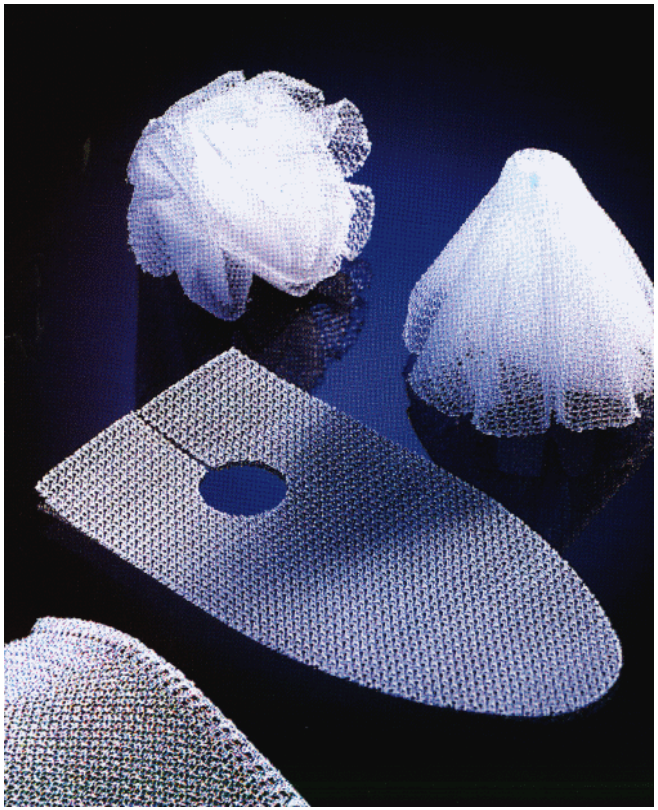
Textile devices for abdominal wall hernia

(stripe, plug or net)

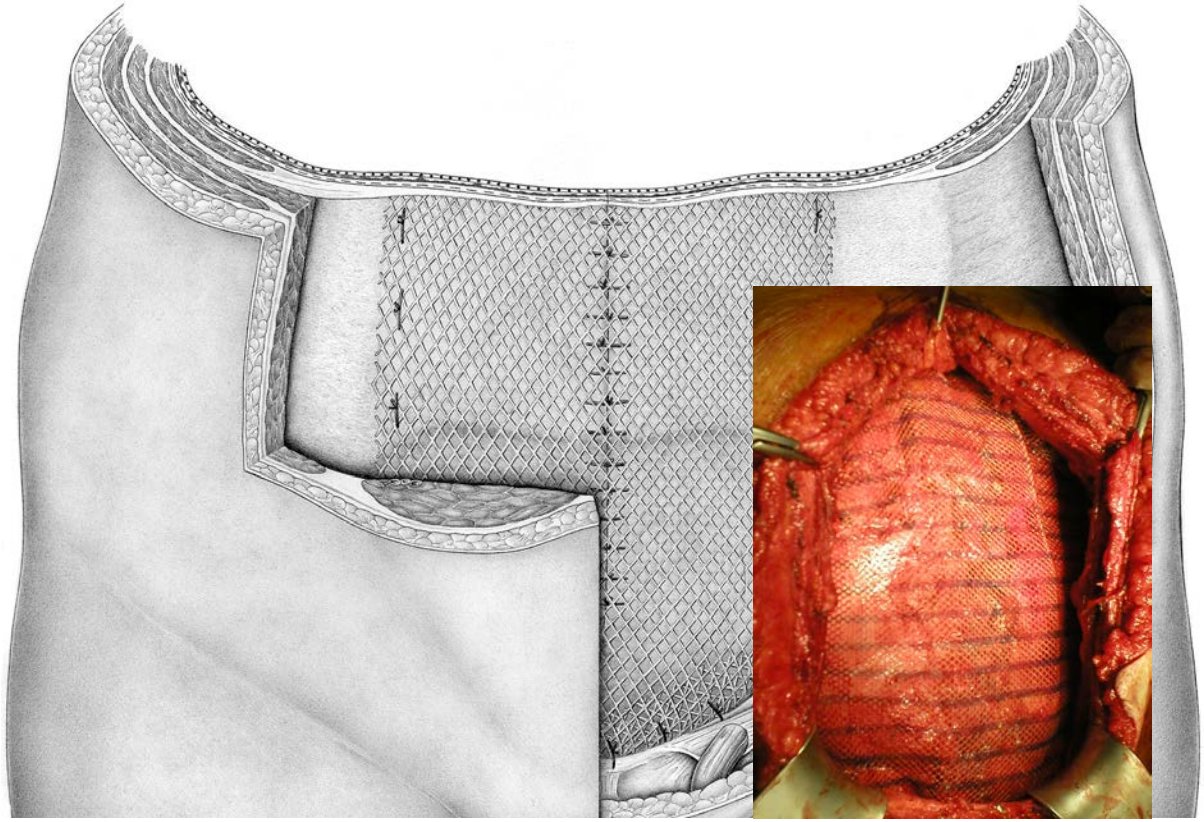
- Experiences in surgery since 1959
  - High recurrence rate with suture repair
  - Smal plugs with high recurrence rate
  - The smaller the net, the higher the risk for recurrence = successful mesh repair depends on overlap
  - Use of large meshes for the repair of abdominal wall hernia
    - Tension free
    - Permanent reinforcement of local tissue
    - and of the entire scar because of defective scar formation
    - Problem: seroma, (late) infection, chronic pain, chronic wound (FBR)
    - Solution: large pore mesh with adjusted elasticity and strength, reduced surface and material, less inflammation and less fibrosis

Meshes for hernia repair

1958:	introduction of *Meshes* by Usher (6 dogs)
since 1969:	Development of various open techniques for hernia repair
since 1986:	Lichtenstein technique for groin hernia
since 1992:	endoscopic procedures TAPP/TEP/IPOM



Various meshes



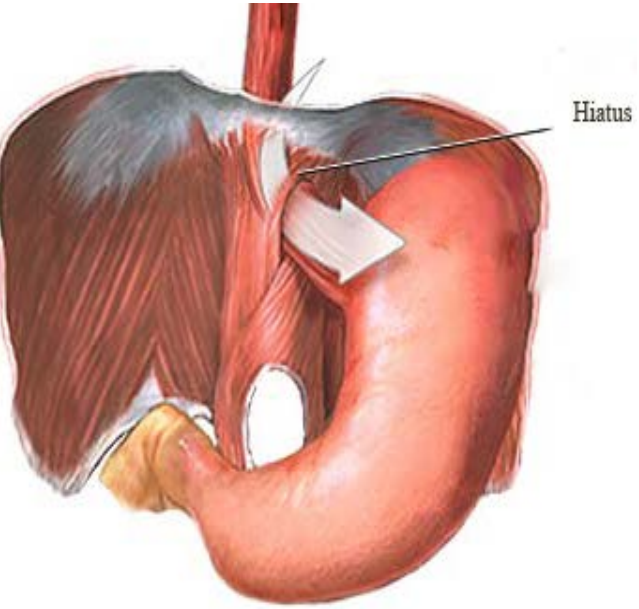
Preperitoneal *mesh*-plasty

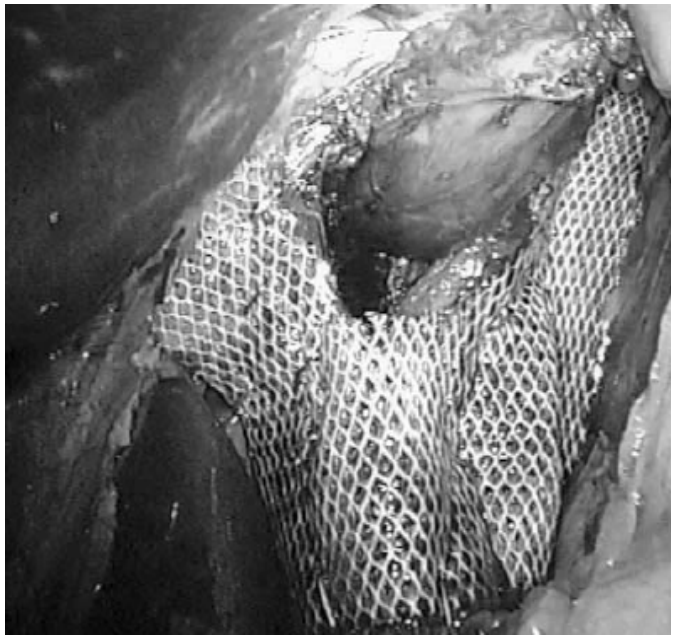
Textile devices in the abdominal cavity

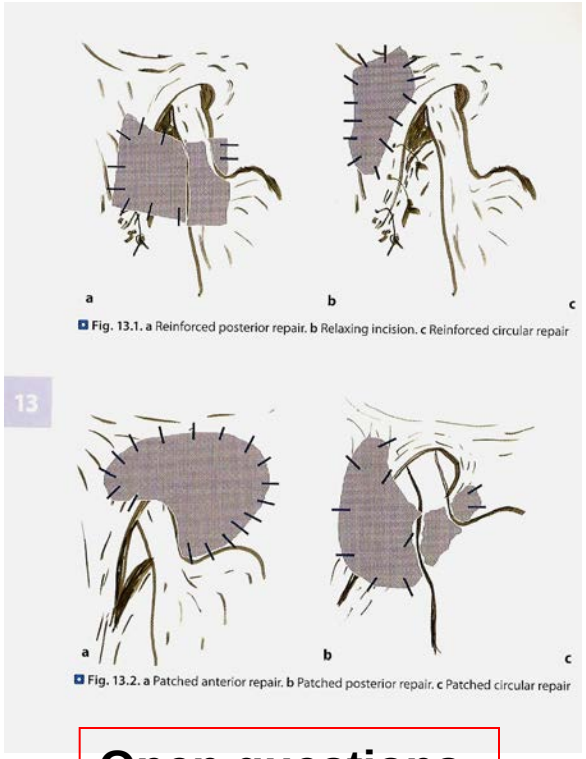
- Gastric banding, Reinforcement of the hiatus (GERD) with sling/band (tension free?)
  - Problem: migration, erosion
  - Possible solutions
    - Stretchable filaments ?
    - Stable form even unter strain ?
    - Optimal fibre geometry for minimal pressure to the filaments?
    - Meshes visible in MRT?

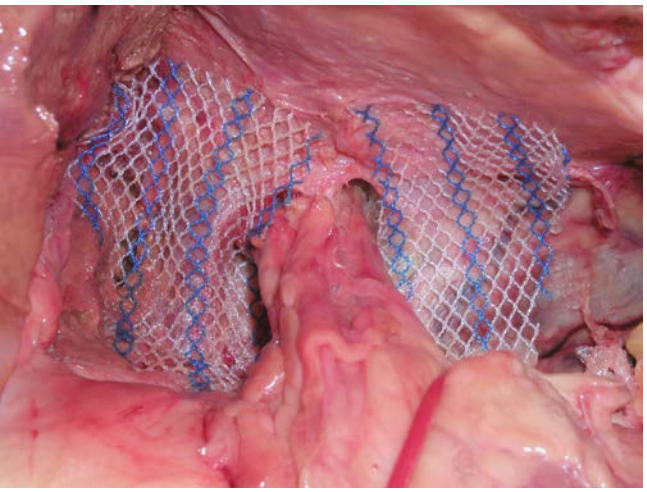
- Fundamental issue for the use of textile devices:
  - „Reinforcement of an area with a mesh“
    or
  - Reconstruction of stability by „tension banding with a sling“ ?

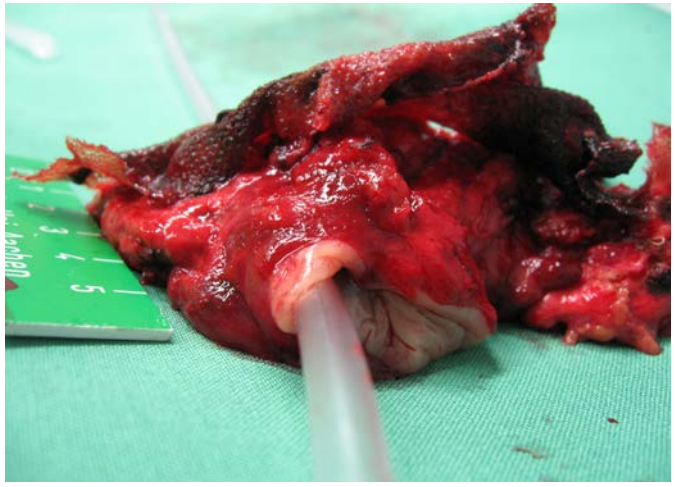
Therapy of an hiatal hernia with mesh – risk for erosion and migration







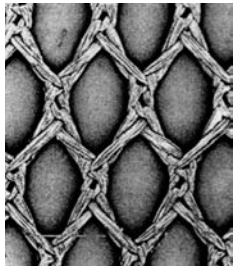
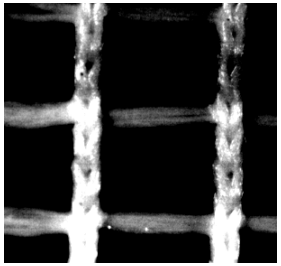
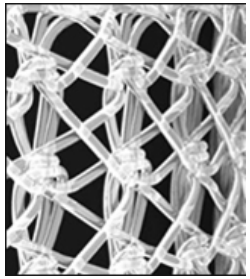
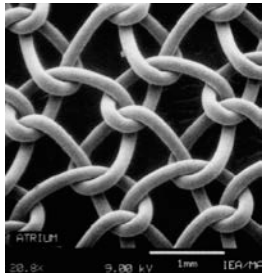




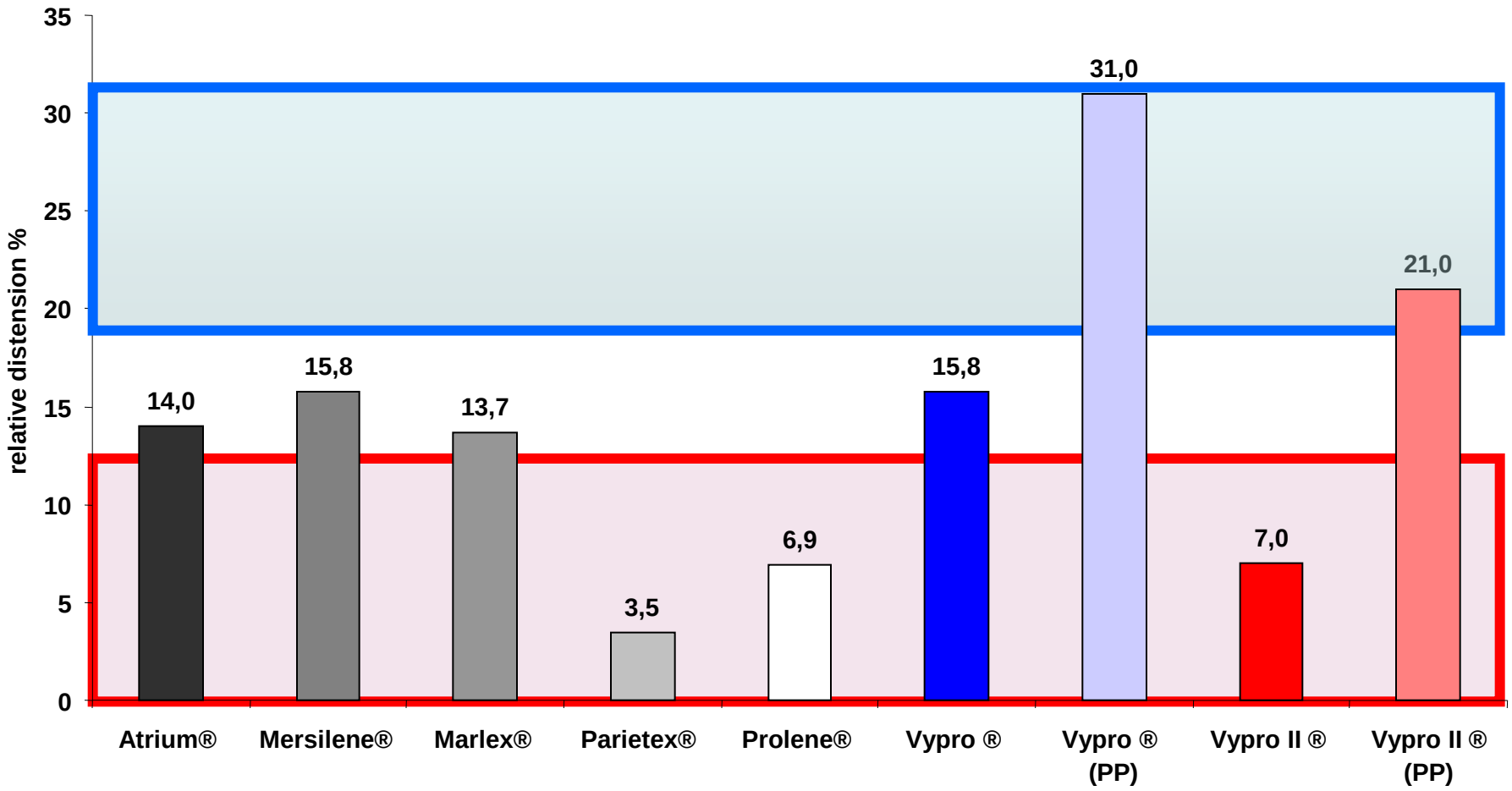
Open questions:
collagen ?
PP ?
PTFE ?
circular ?
sling ?
fixation ?

Textile charakteristics of meshes

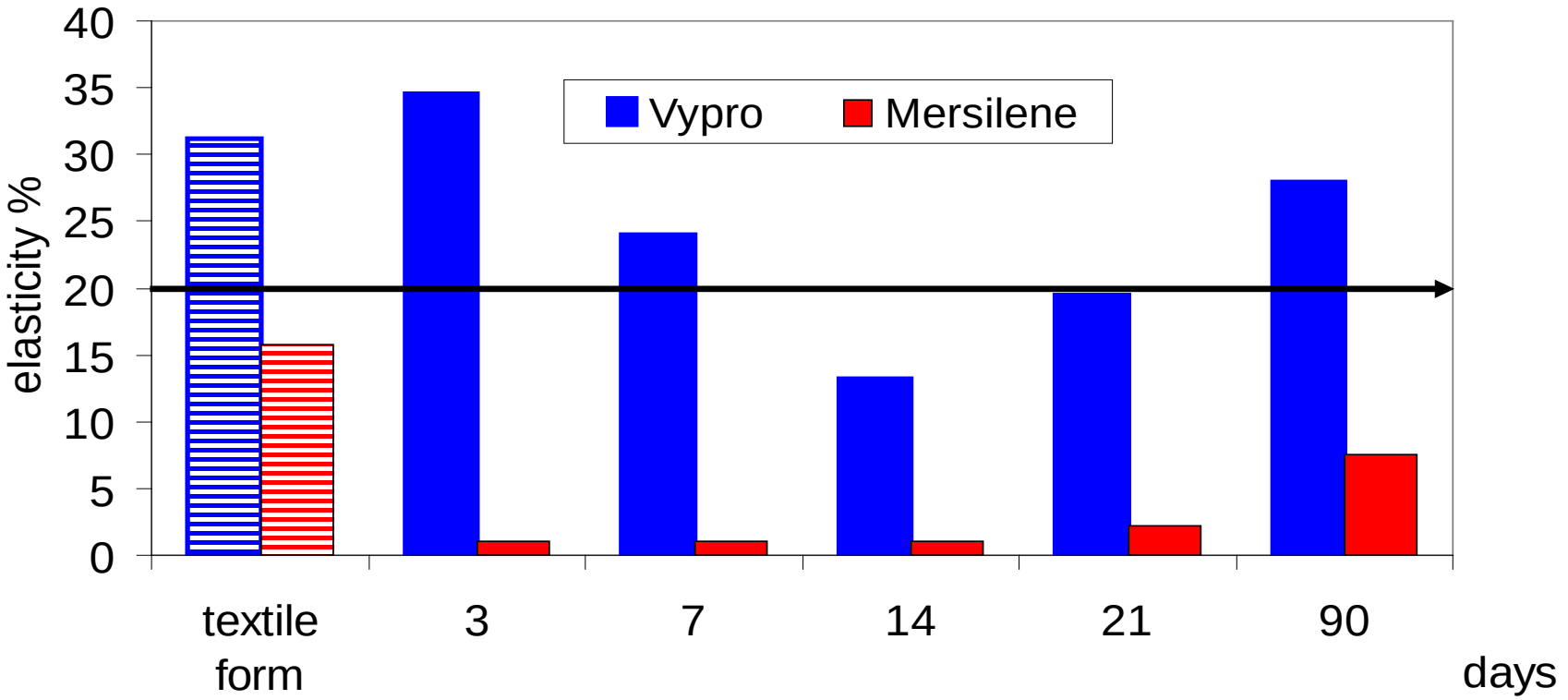
Trade name	Mersilene	Parietex	Prolene	Marlex	
Weight [g/cm^2]	**39,5**	**129,6**	**108,5**	**95,09**	
Stiffness [cN]	0,38	9,98	6,71	34,66	längs
	0,06	24,21	12,89	134,39	quer
Force tearing out a seam [N]	15,2	68,5	57,0	57,2	längs
	15,5	55,4	74,6	55,8	quer
Subsequent tearing force [N]	0,64	3,36	**0,05**	0,66	längs
	0,68	2,78	**4,41**	4,03	quer
Maximal force pressing through a stamp [N]	19,54	90,38	90,93	58,8	

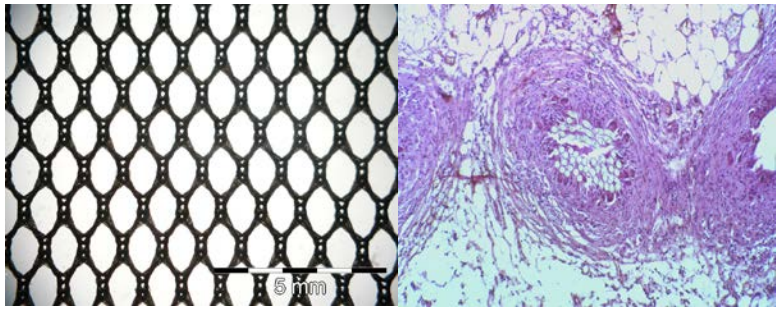





Elasticity of textile meshes

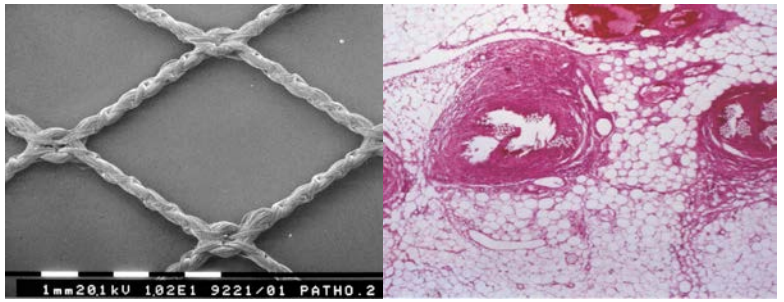


Elasticity of incorporated meshes in rats





small pores

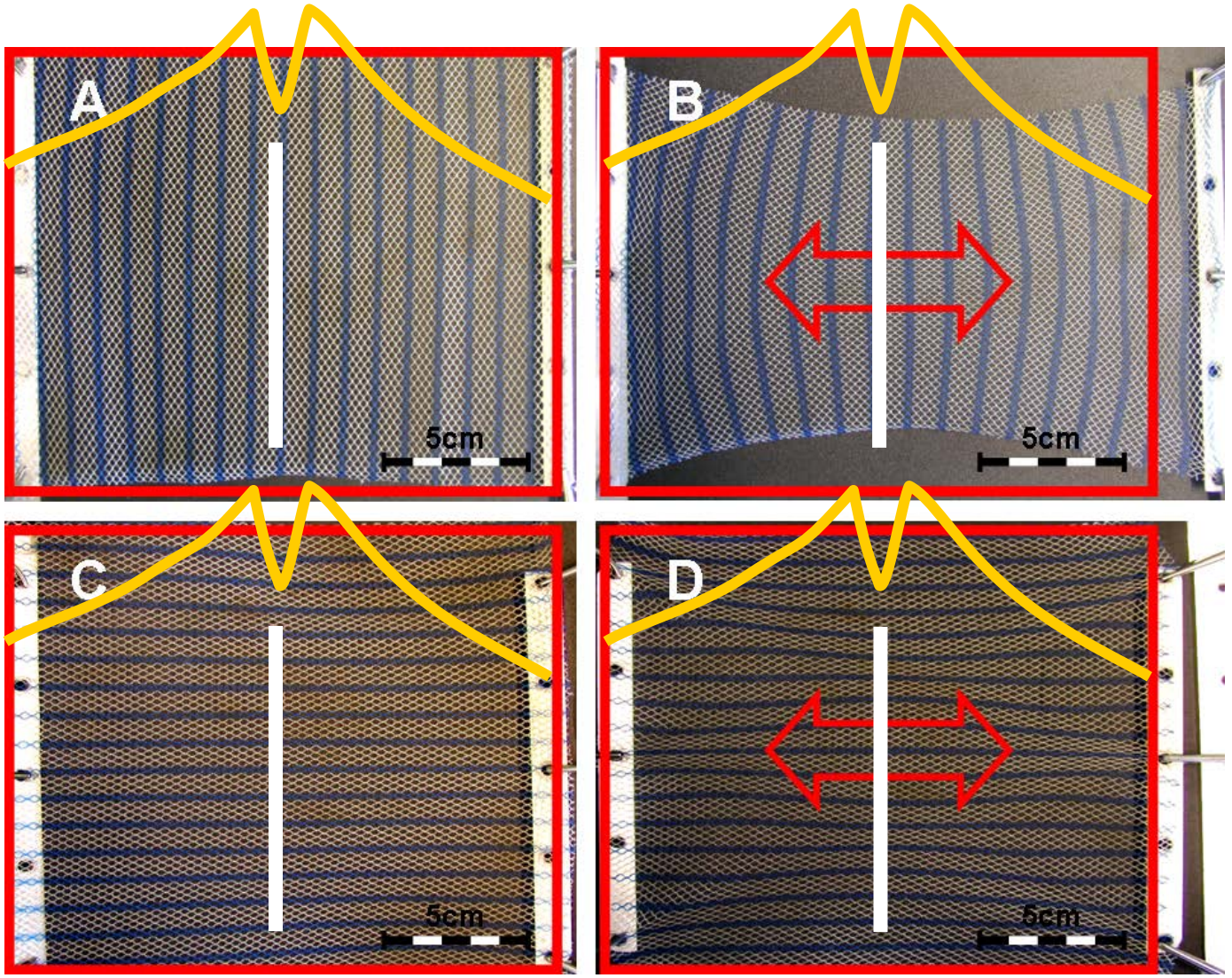


large pores

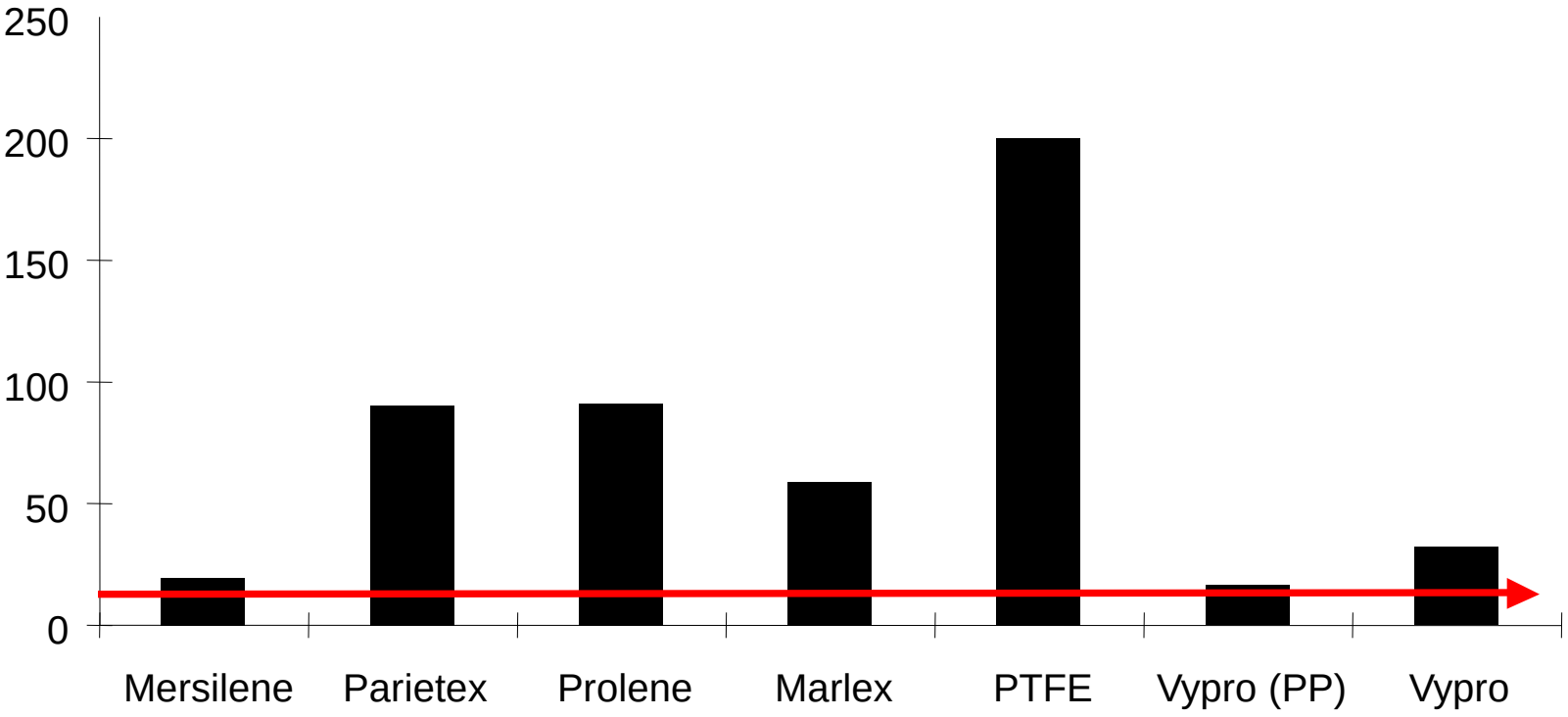
Stretchability and overlap

Stretchability in horizontal direction: Reduction of overlap in vertical direction

Stretchability in vertical direction: No reduction of overlap in vertical direction



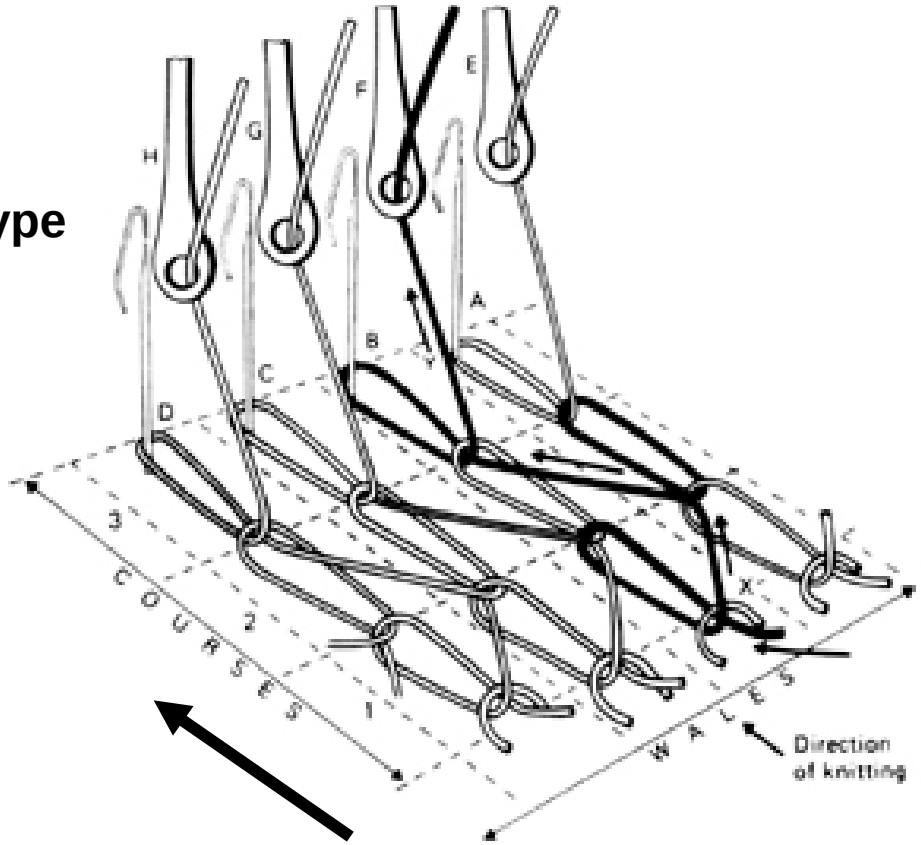
Tensile strength of meshes

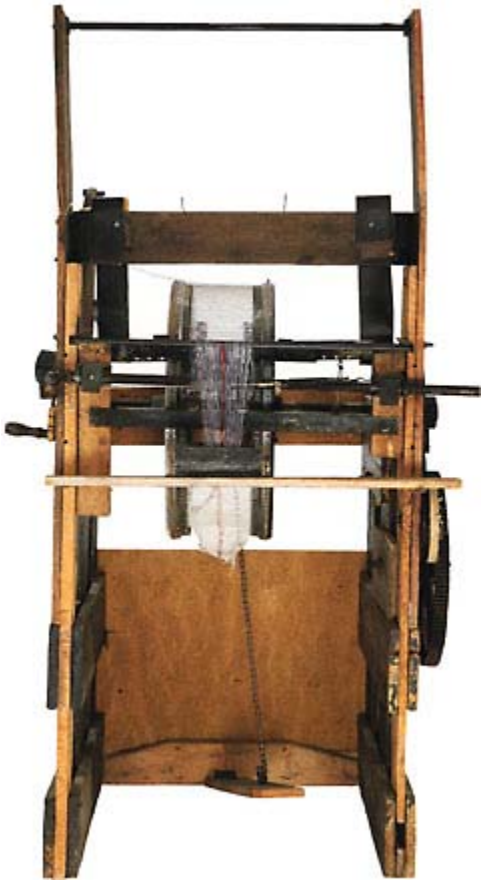


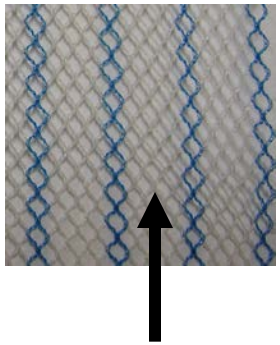
- Tensile strength of suture repair in the groin
  - Lipton 1994: 1,3 N/cm
  - Read 1982: 0,5 - 2 N/cm
  - Wantz 1985: 0,1 - 0,3 N/cm
  - Peiper 1998: 0,5 N/cm

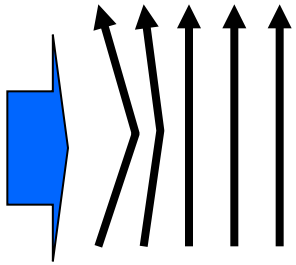
Principle of textile hosieries

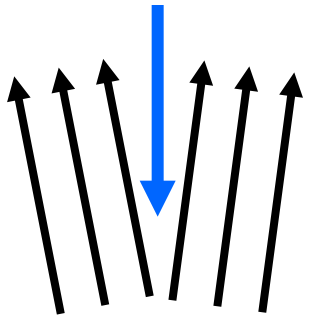
Subsequent tearing force result from type of weaves
=
resistance to splitting !



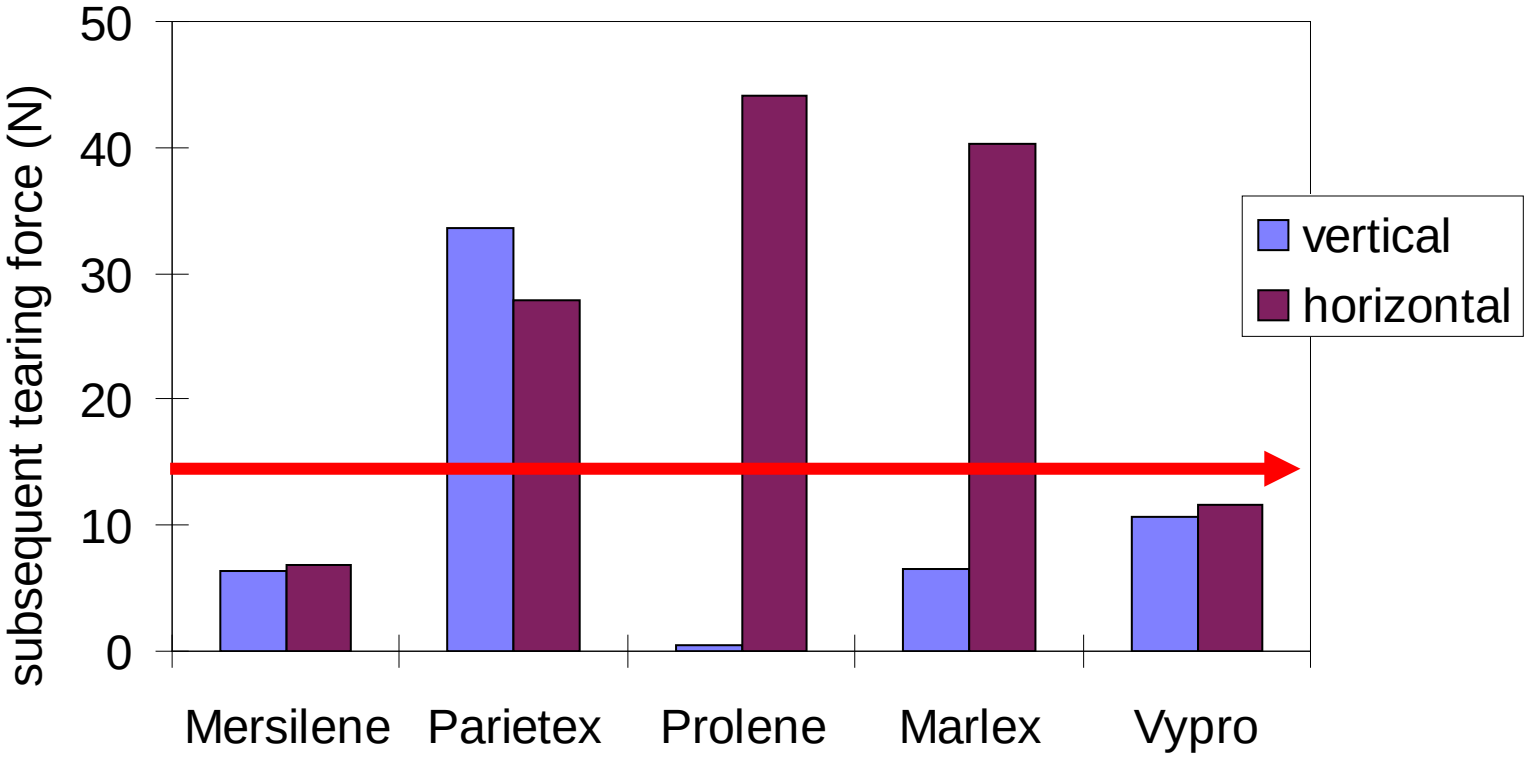








Subsequent tearing force

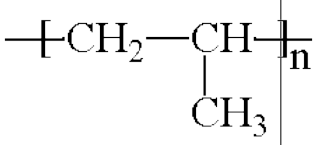


*May explain recurrences in case of **slit mesh***

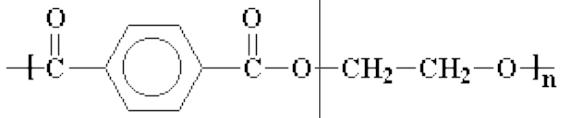
- indirect recurrence (TAPP, Lichtenstein) ?
- parastomal recurrences ?
- failured suture of the mesh in case of revision operation ?

Polymers used for hernia meshes

- polypropylene (PP)
  Marlex®, Prolene®, Atrium®, Premilene®, Vypro®

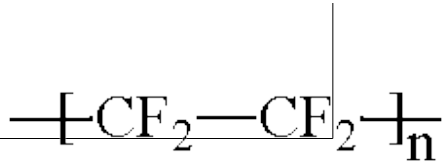


- polyethylene terephthalate (Polyester)
  Mersilene®, Parietex®



- polyvinylidenfluoride (PVDF)

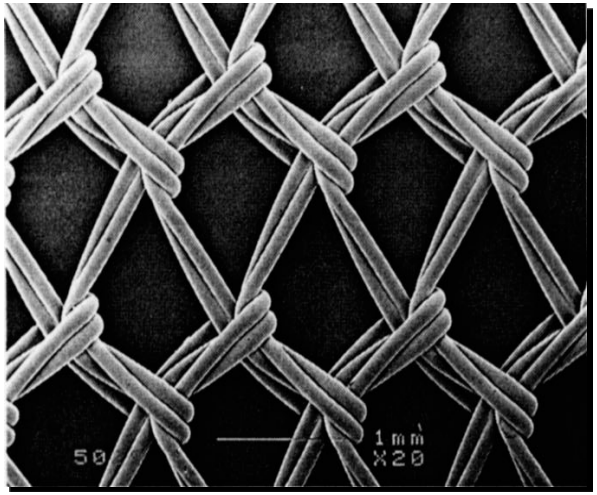
- polytetrafluorethylene (ePTFE)
  DualMesh ®, GoreTex®



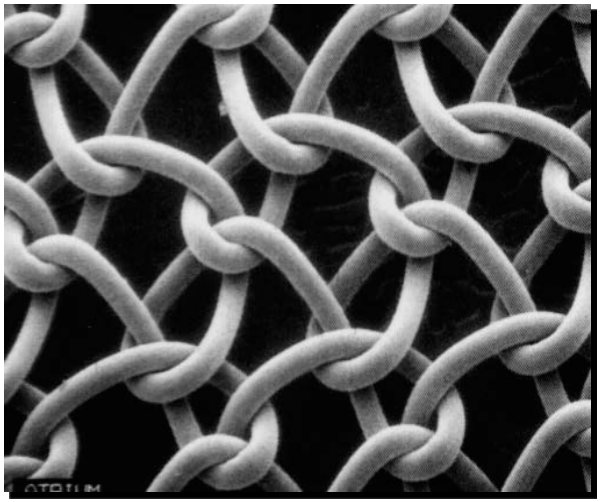
(biologic materials ?)

Polypropylene

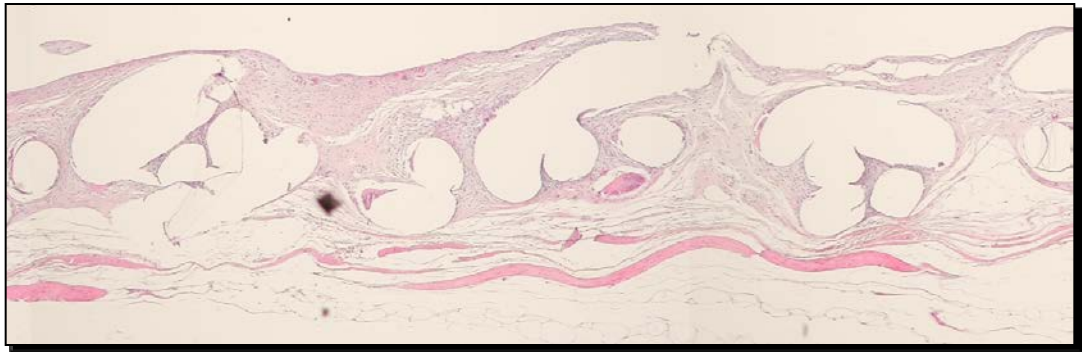
- In den ersten 2-3 Wochen akut-entzündliche Fremdkörperreaktion
- Nach 3 Wochen chronische FKR
- Wegen hoher Biegesteifigkeit der Monofilamente rel. offene Bindungen
- Langfristig Einsteifung und Oberflächenschäden
- Geringe Kosten für das Polymer
- Narbiges „bridging“ bei Poren < 600-800 µm



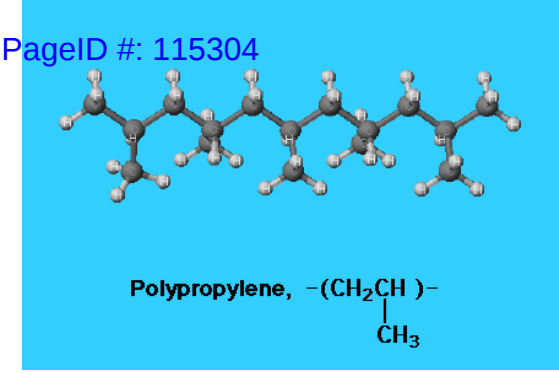
Prolene



Atrium



Polypropylene



- Process of polymerisation
  - orientation of CH_3-attachment to one single side: *isotactic*
  - alternating up/down: *syndiotactic*
  - random: *atactic*
- **In its pure form** polypropylene is **inappropriate**
  - very light
  - brittle
  - inflammable
  - shows rapid softening at higher temperatures
  - rapid degeneration
  - by UV radiation turning into powder within 1 year
- **Only by addition of stabilisator** (z.B. Chalk, soot, mica, glass, ethylene)
  - resistant to heat and autoclavable
  - resistance to fatigue
  - dense and flexible
  - translucent and little inflammable
- Prestretching increases tensile strength
- **What type of „polypropylene“ is used for our meshes ???**

C. R. Costello, S. L. Bachman, B. J. Ramshaw, S. A. Grant:
Materials Characterization of explanted polypropylene hernia meshes
Journal of Biomedical Materials Research Part B: Applied Biomaterials, Published Online: 6 Feb 2007 *(Kugel patch)*

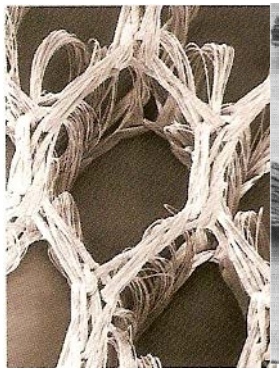
*„The SEM micrographs displayed images of materials that were vastly different in topology than the pristine materials. The micrographs of explanted **polypropylene** materials exhibited cracks, surface roughness, and peeling indicative of **surface degradation**, while the pristine materials appeared smooth.“*

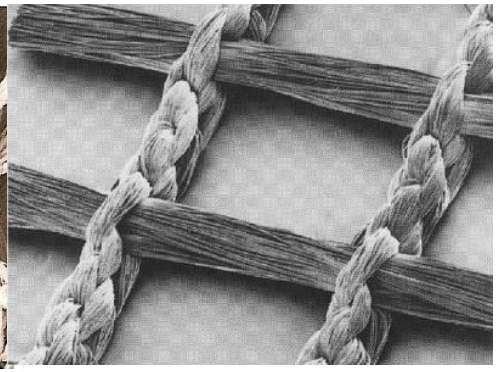
Polypropylene

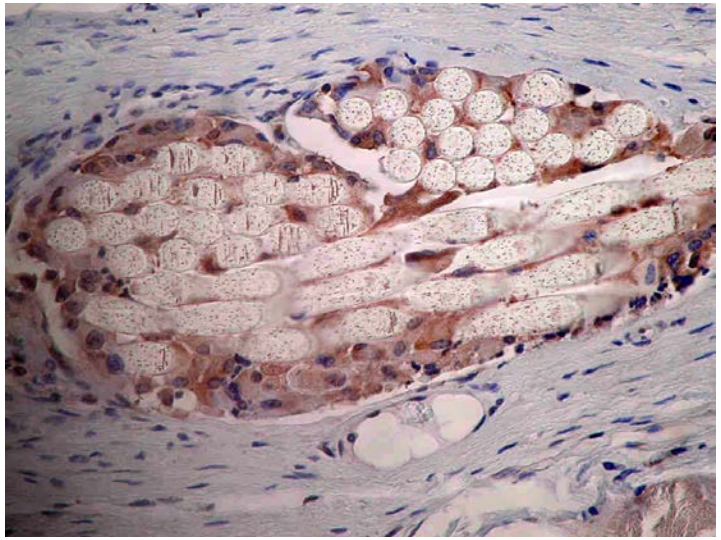
- Standard polymer for meshes
- Slow elongation
- increased stiffness over time
- slow degradation
- Acute inflammatory foreign body reaction
- Intra-abdominal adhesions
- Risk for migration due to increased cell turn over at the interface ?

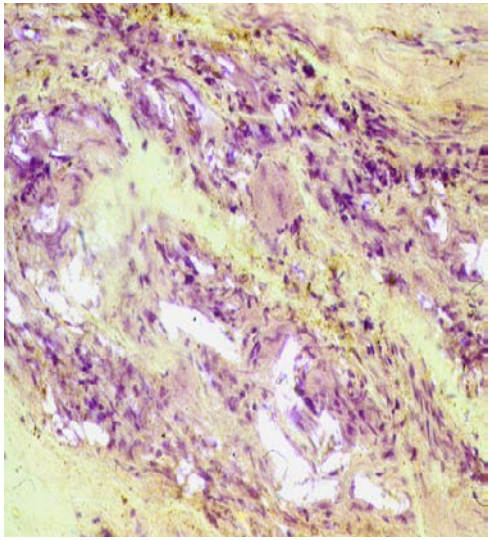
Polyester

- multifilament (infection ?)
- degradation
- seroma
- Initially moderate acute inflammatory FBR
- cells penetrate fibre









MMP-2, rat, 90 days

Immune response against polyester implants is influenced by the coating substances

Lutz Wilhelm,[1]* Roland Zippel,[2]* Thomas von Woedtke,[3] Heidrun Kenk,[4] Andreas Hoer
Maciej Patrzyk,[1] Michael Schlosser[5]
[1]Department of Surgery, University of Greifswald, Greifswald D-17487, Germany
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[4]Institute of Pathophysiology Karlsburg, University of Greifswald, Greifswald
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Received 2 July 2005; revised 29 August 2006; accepted 11 Octobe
Published online 23 March 2007 in Wiley InterScience (www.in 0.1002/jbm.a.31209

clinical relevance ?

Through this inve e able to show that the implantation of polyester pro duced a significant humoral immune reaction.

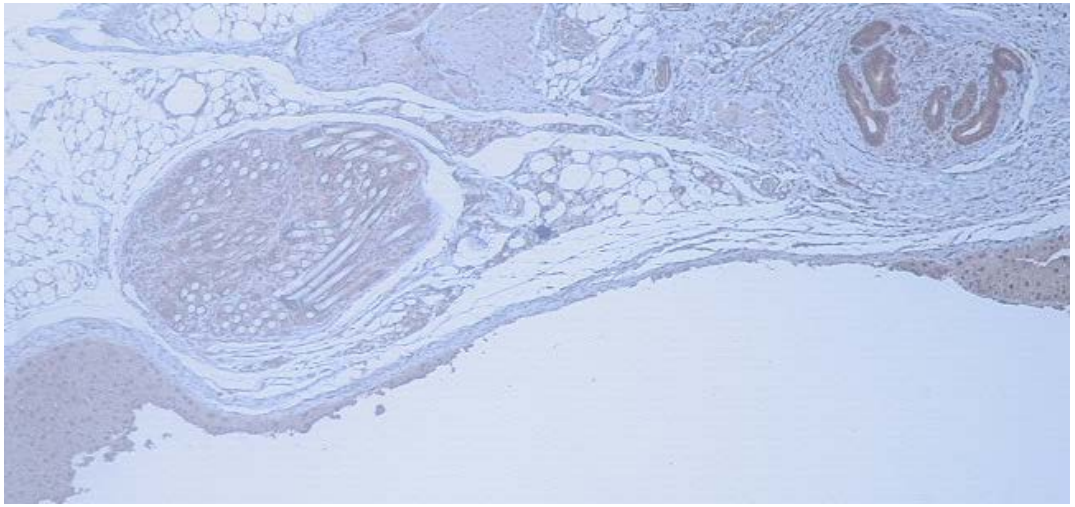
Polyester

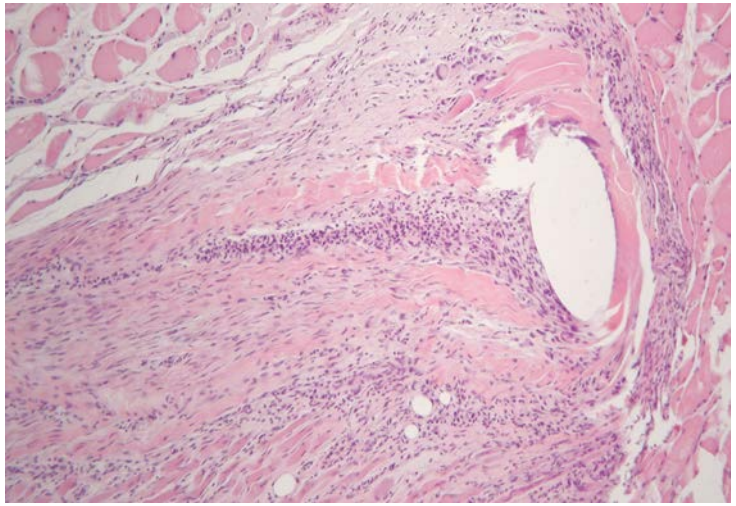
	Polyester	Polypropylene/PTFE
Fistula	16 %	0 - 2 %
Infection	16 %	0 - 6 %
Recurrence	34 %	10 - 14 %

Leber, Gorb, Alexander, Reed 1998, Springfield Mass.
Follow-up 6.7 years, 200 inc. hernia (138 PP, 32 Polyester, 30 PTFE)
in Arch Surgery 133: 378-382

Polyester

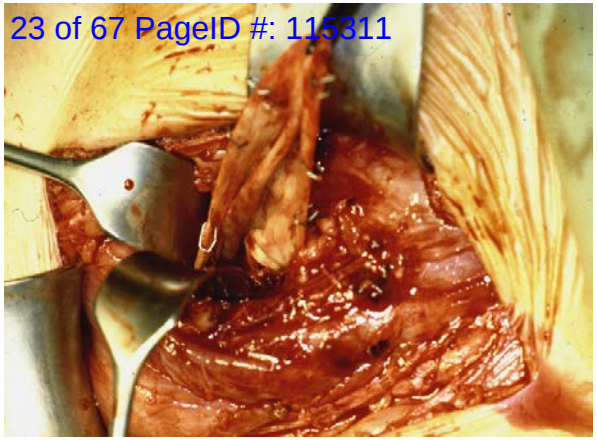
- Standard polymer for vascular grafts
- degradation (surface↑) ?
- Multifilaments with increased risk for infection ?
- Multifilaments with reduced perifilamentary necrosis ?
- Human antibodies ?

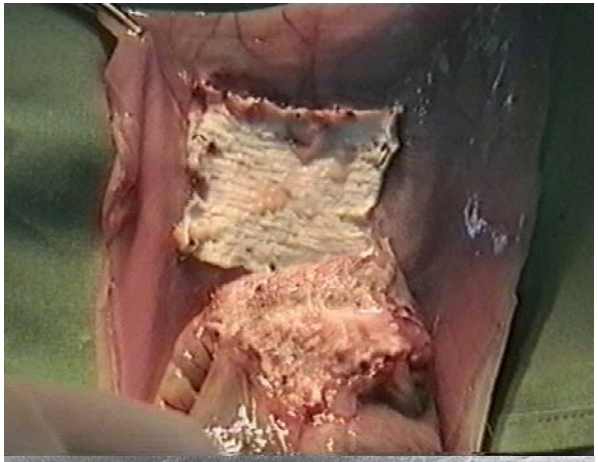


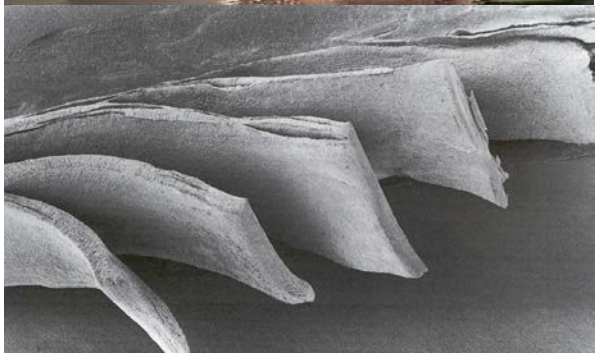


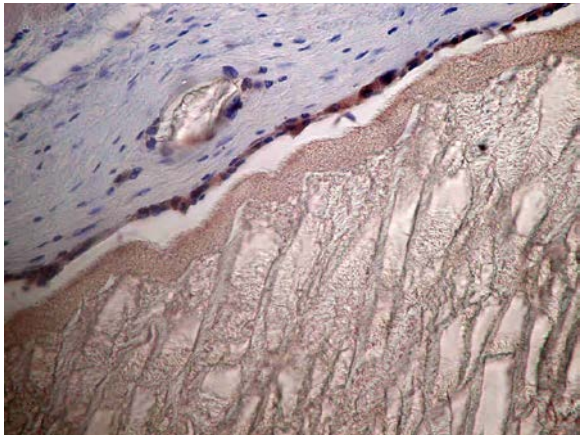
ePTFE

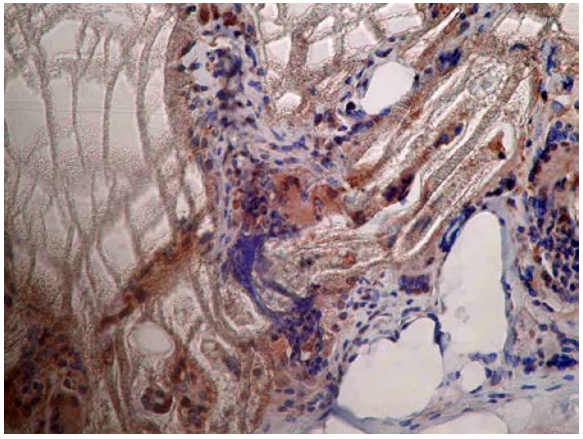
- rather „film“ than porous net
- little adhesions
- long-term degradation ?
- prone for infection (Il-10 ↑)
- expensive











MMP-2 rat 90 days

Major mesh-related complications following hernia repair

Events reported to the Food and Drug Administration

T. N. Robinson[1] ✉, J. H. Clarke[1], J. Schoen[1] and M. D. Walsh[1]

Surg Endosc. 2005 Dec;19(12):1556-60

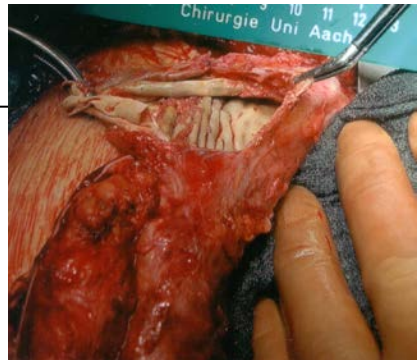
Table 1. Major complications related to mesh material types

	All mesh (%)	PP (%)	COMP (%)	Sepra (%)	PTFE (%)	BIO (%)
Infection	42 (107)	43	42	13	75†	29
Mechanical failure	18 (46)	17	12	80*	0	0
Pain	9 (23)	10	11	0	13	0
Reaction	8 (20)	10	0	0	0	57
Intestinal	7 (18)	4	14*	7	13	0

All mesh, combination of all mesh types reported; PP, polypropylene; COMP, composix mesh, SEPRA, Seprafilm/polypropylene mesh; PTFE, expanded polytetrafluoroethylene; BIO, combination of all mesh created from human or animal collagens; Reaction, foreign body reaction; Intestinal, intestinal complications including fistula and bowel obstruction

*$p < 0.05$

†$p = 0.07$



Excerpta Medica

The American Journal of Surgery

The American Journal of Surgery 184 (2002) 154–159

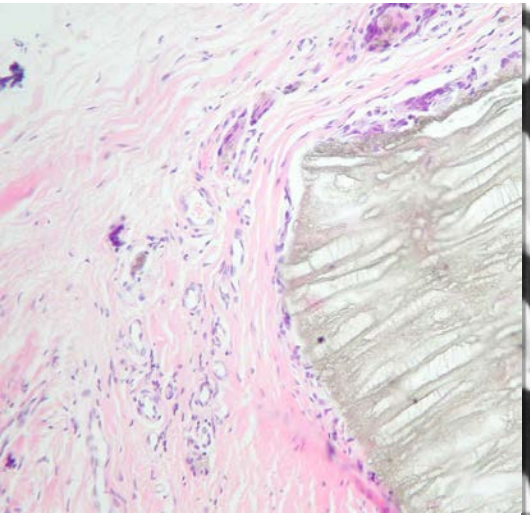
Scientific paper

The structure of a biomaterial rather than its chemical composition modulates the repair process at the peritoneal level

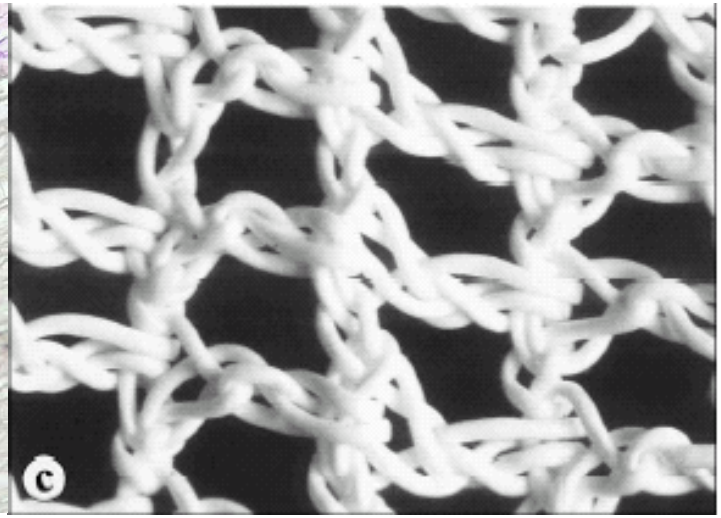
Juan M. Bellón, Ph.D.*, Francisca Jurado, Ph.D., Natalio García-Honduvilla, Ph.D., Raquel López, M.D., Antonio Carrera-San Martín, Ph.D., Julia Buján, Ph.D.

Department of Morphological Sciences and Surgery (Surgical Research Laboratory), Faculty of Medicine, University of Alcalá, Crta. Madrid-Barcelona, km 33.6, 28871 Alcalá de Henares, Madrid, Spain

Manuscript received November 28, 2001; revised manuscript April 29, 2002



ePTFE sheath, 10 years



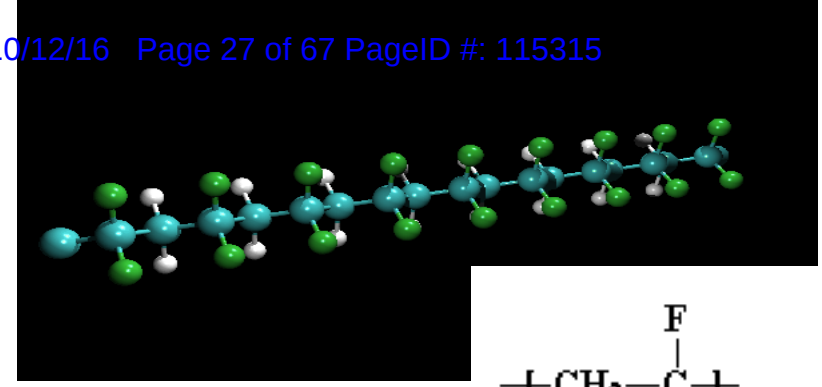
(**C**) reticular prosthesis composed of ePTFE suture thread (CV-4).

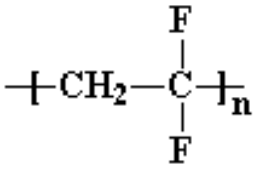
„The inflammatory response induced by this material was extensive.“

ePTFE

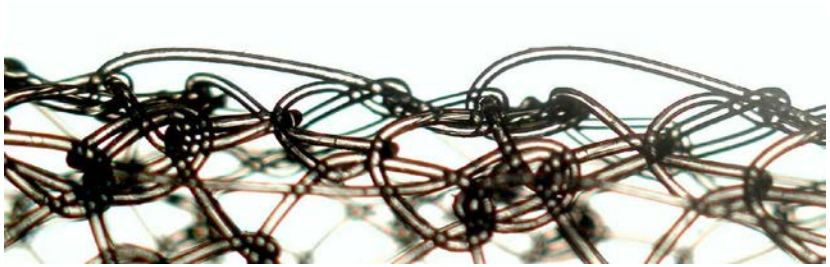
- Standard polymer for vascular grafts
- degradation ?
- infection ↑
- shrinkage
- no elasticity
- New devices with large pore nets of PTFE ?

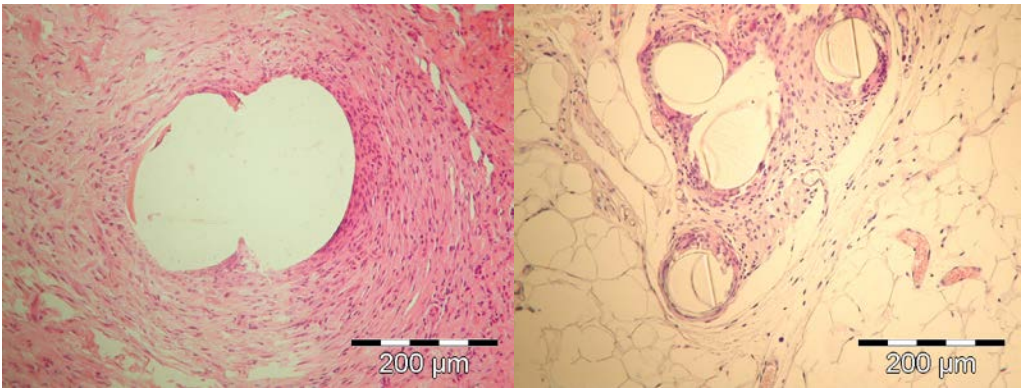
PVDF





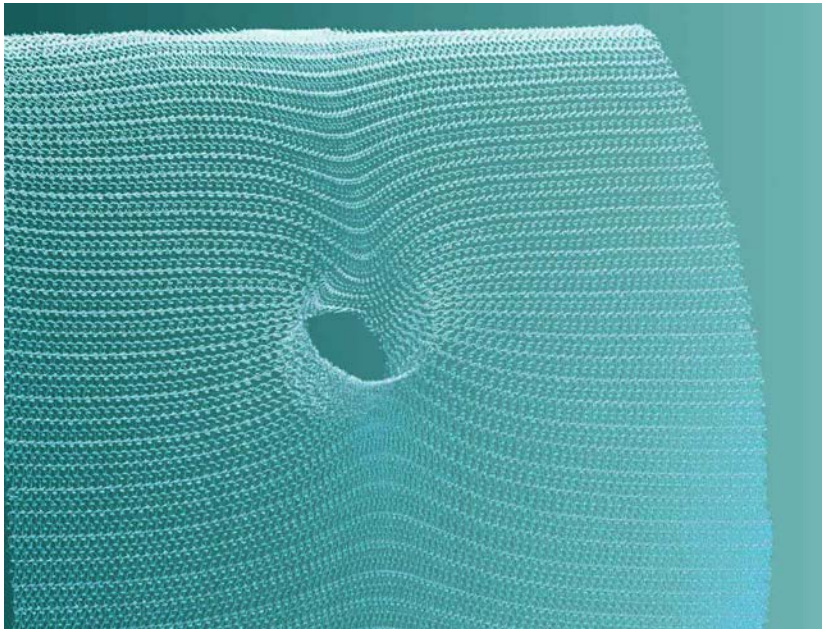
- **Stronger than PP**
- **Heavier than PP**
  Polypropylene 0.9 g/cm³
  Polyvinylidenfluoride 1.8 g/cm³
- **More resistant than PP to degradation**
- **Little inflammatory activity**
- **Decreased risk for bridging so that smaller pores can be realized**





Prolene

PVDF



Polyvinylidene Fluoride Monofilament Sutures: Can They Be Used Safely for Long-Term Anastomoses in the Thoracic Aorta?

Gaétan Laroche, Yves Marois, Erwin Schwarz, Robert Guidoin, Martin W. King, Edouard Pâris, and Yvan Douville

Département de Chirurgie, Université Laval, Institut des Biomatériaux du Québec, Hôpital Saint-François d'Assise, et Département de Chirurgie, Hôpital du St. Sacrement, Québec, Canada

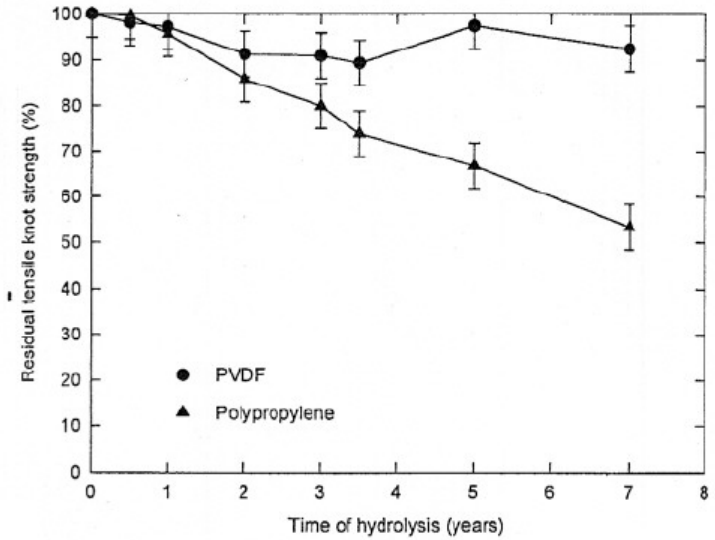


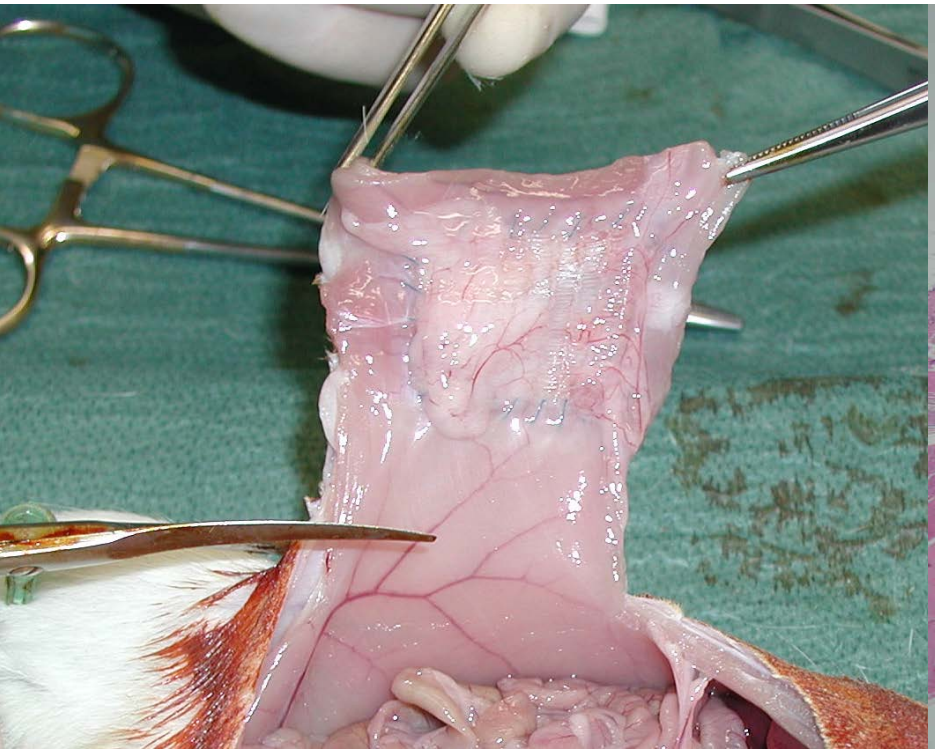
FIG. 5. The residual tensile strength of PVDF and polypropylene sutures during the 7 years of exposure to hydrolytic conditions is illustrated.

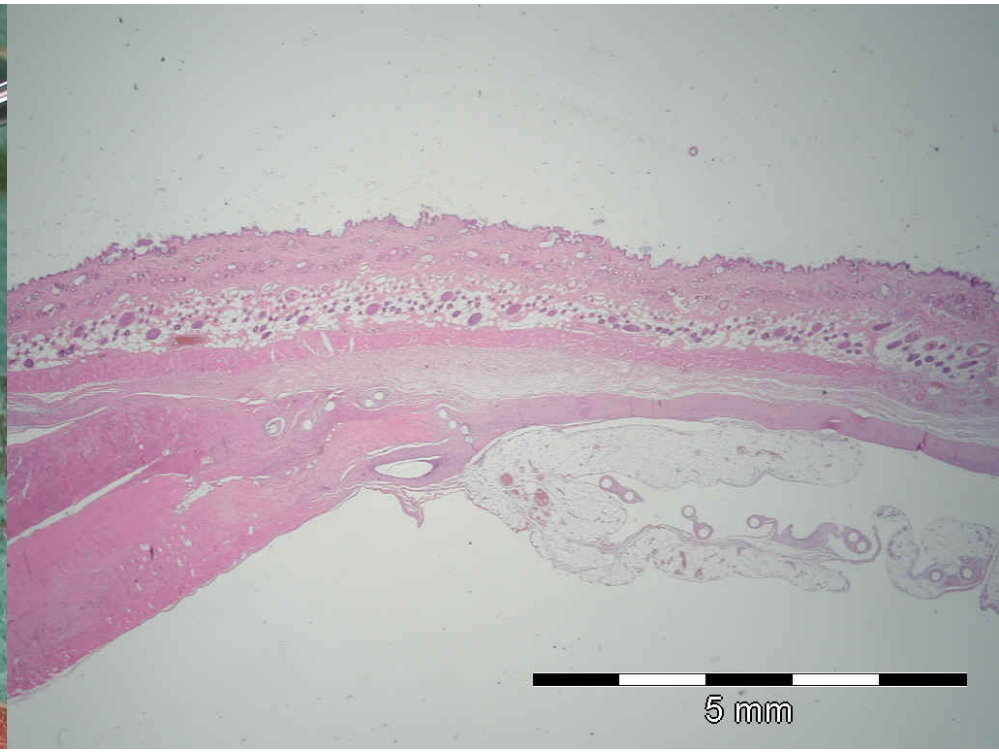
9 years. During incubation, the PVDF polymer experienced molecular rearrangements from a mixture of sor ecules as well as a loss of 46% of its original tensile strength. In contrast, the polypropylene samples showed no crystalline rearrangement but more extensive oxidation and water imbibition, which it is believed were in part responsible for the 46.6% loss of initial tensile strength. The tissue response of the

tensile strength after 9 years
PVDF→92.5 %, PP→53.4 %

Little adhesions to PVDF-IPOM

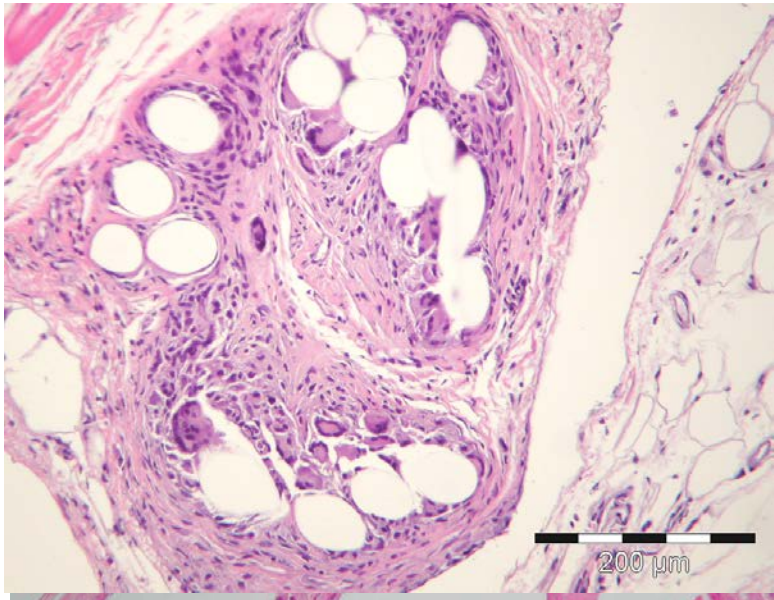
21 days, rat

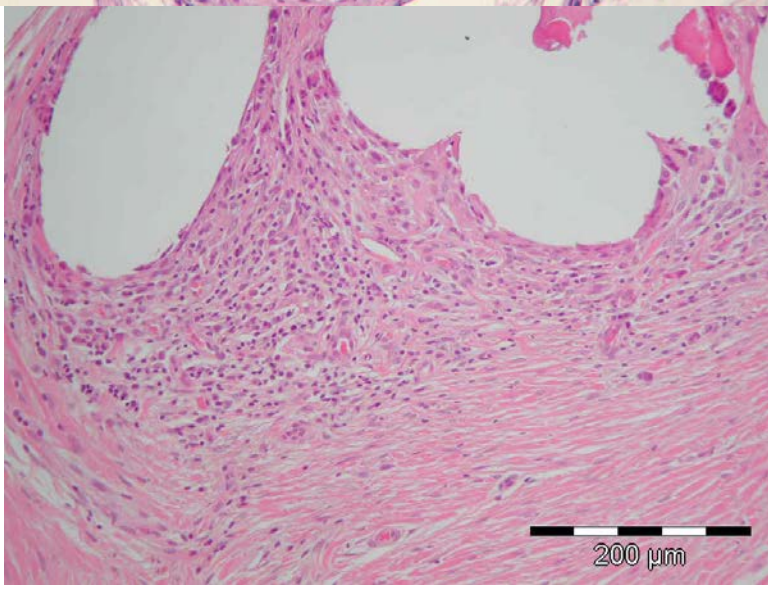




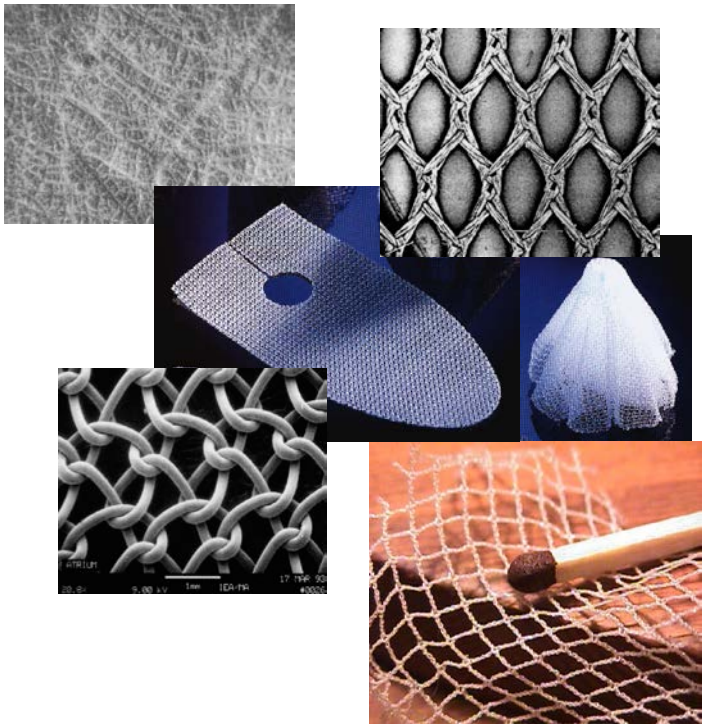
Biological response to implanted meshes

= “chronic wound”

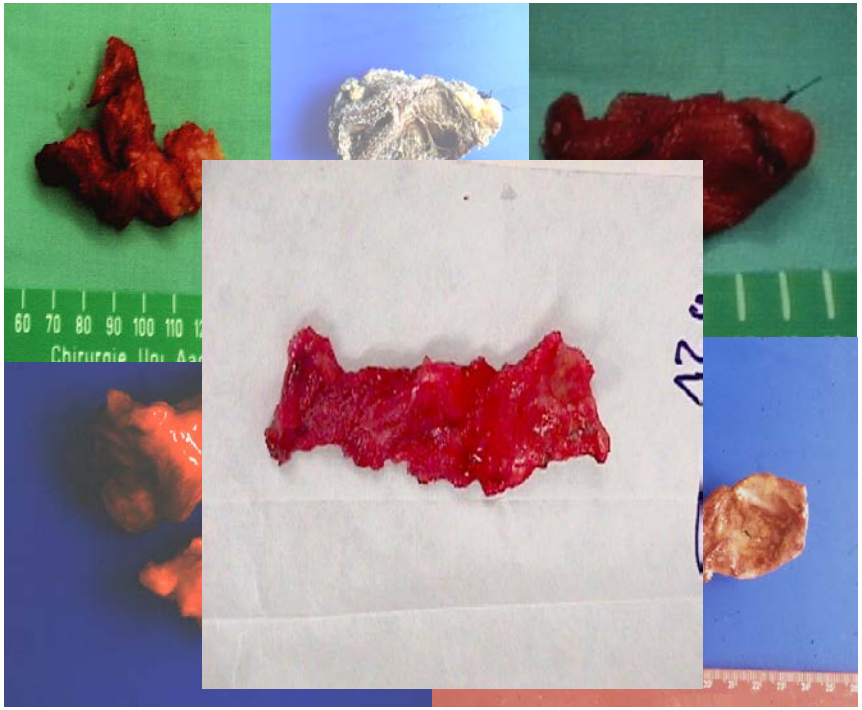




Tissue integration changed mesh appearance

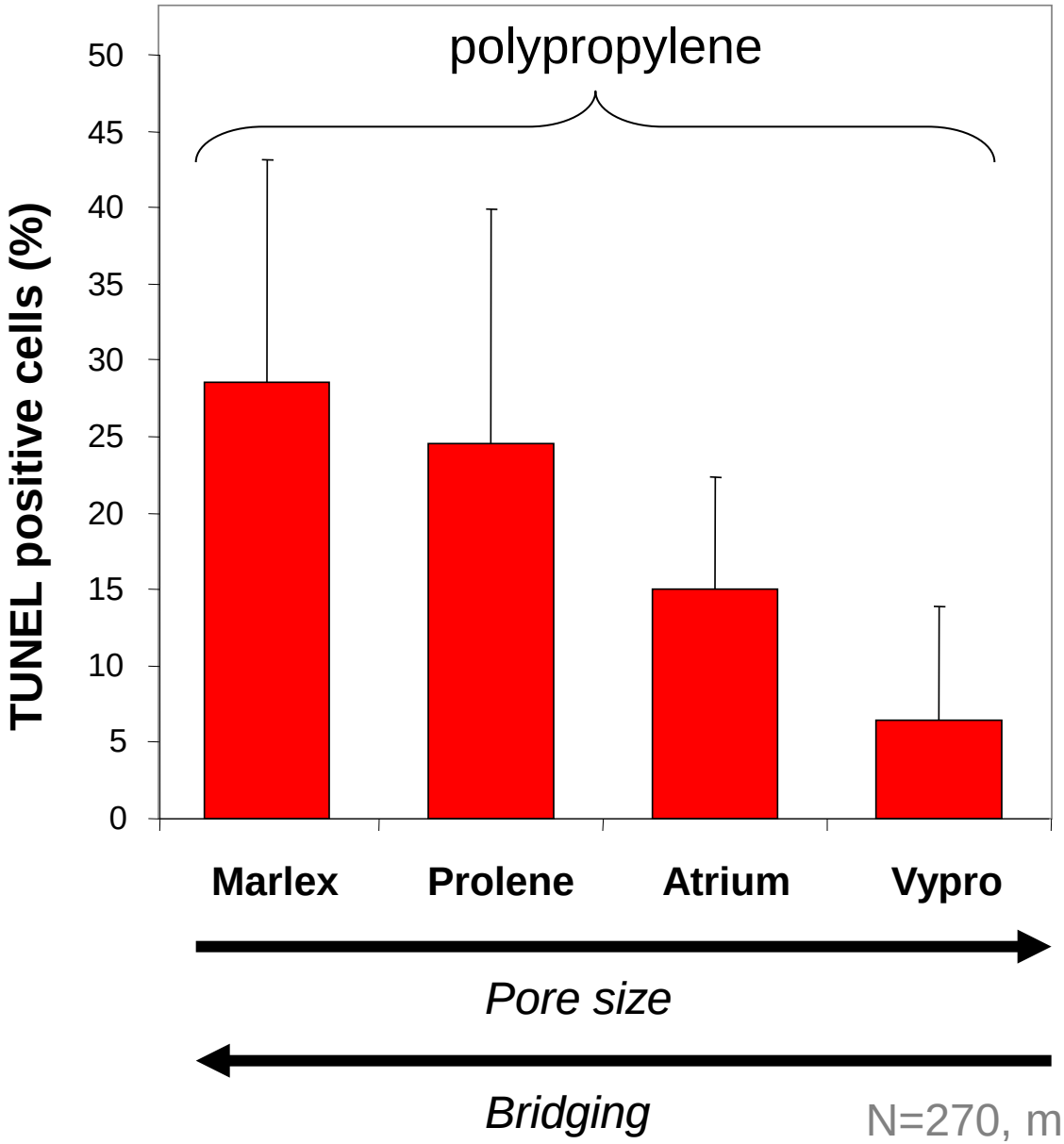


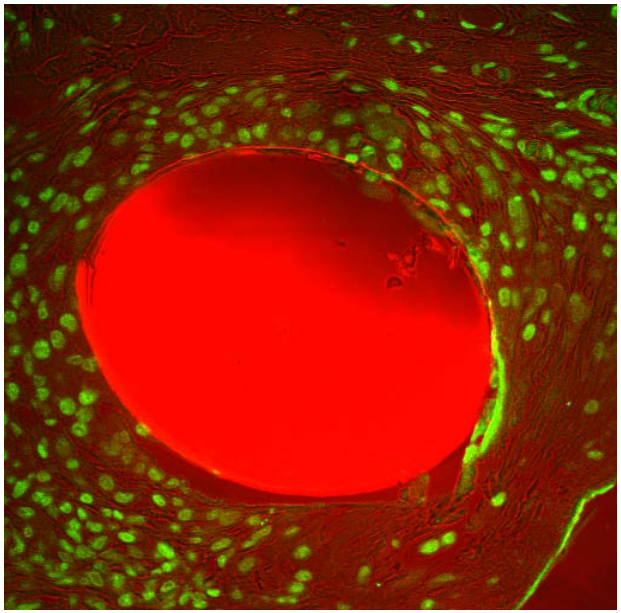
textile meshes



meshes *in vivo*

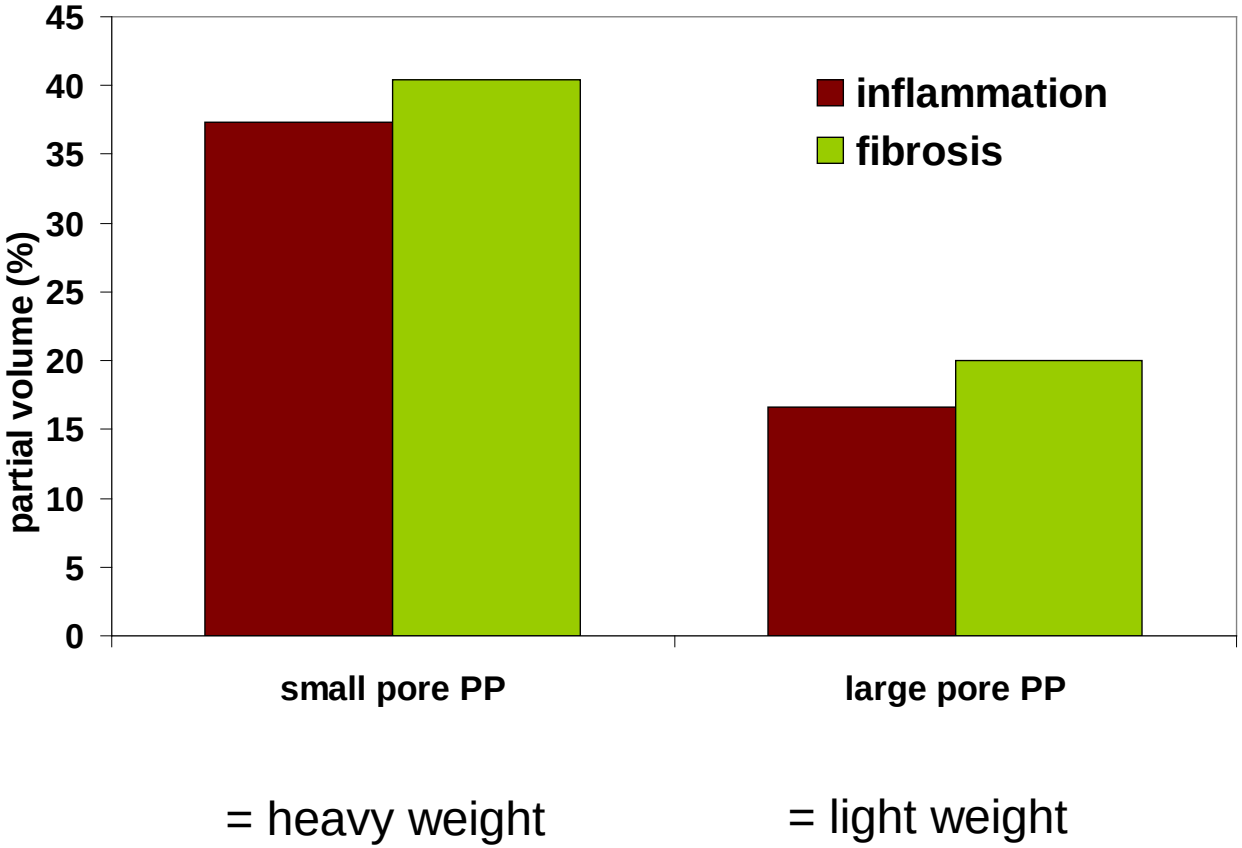
Surface determines apoptosis, not the polymer





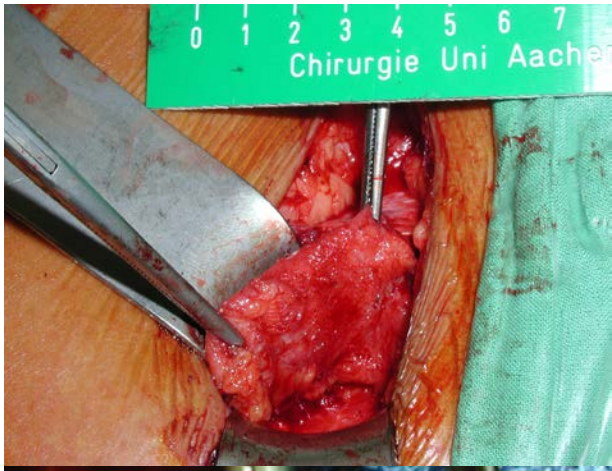
N=270, mean implantation period 2 years

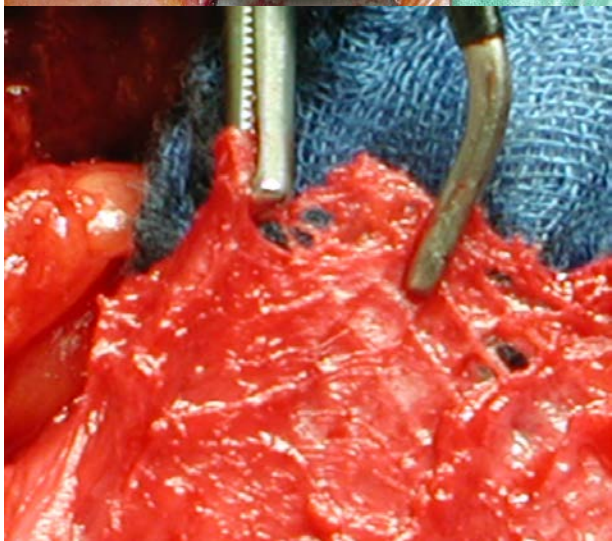
Extent of inflammation and fibrosis depends on mesh structure (*porosity*)



= heavy weight

= light weight

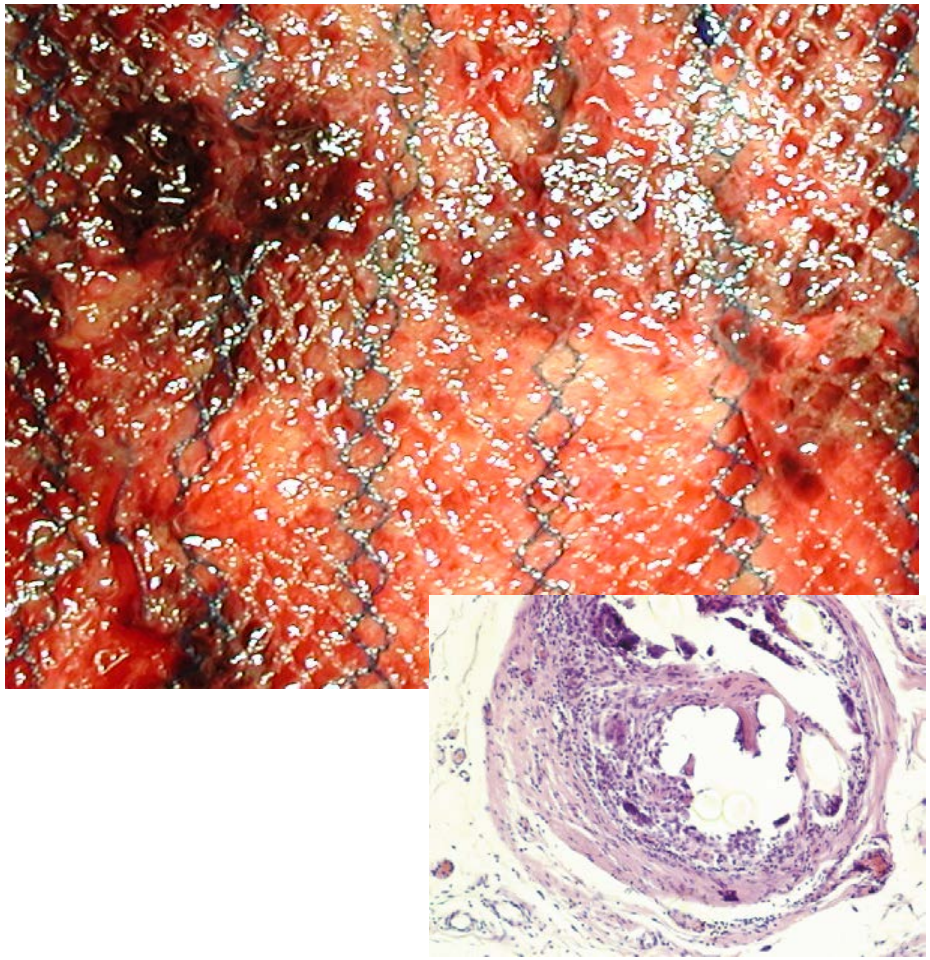




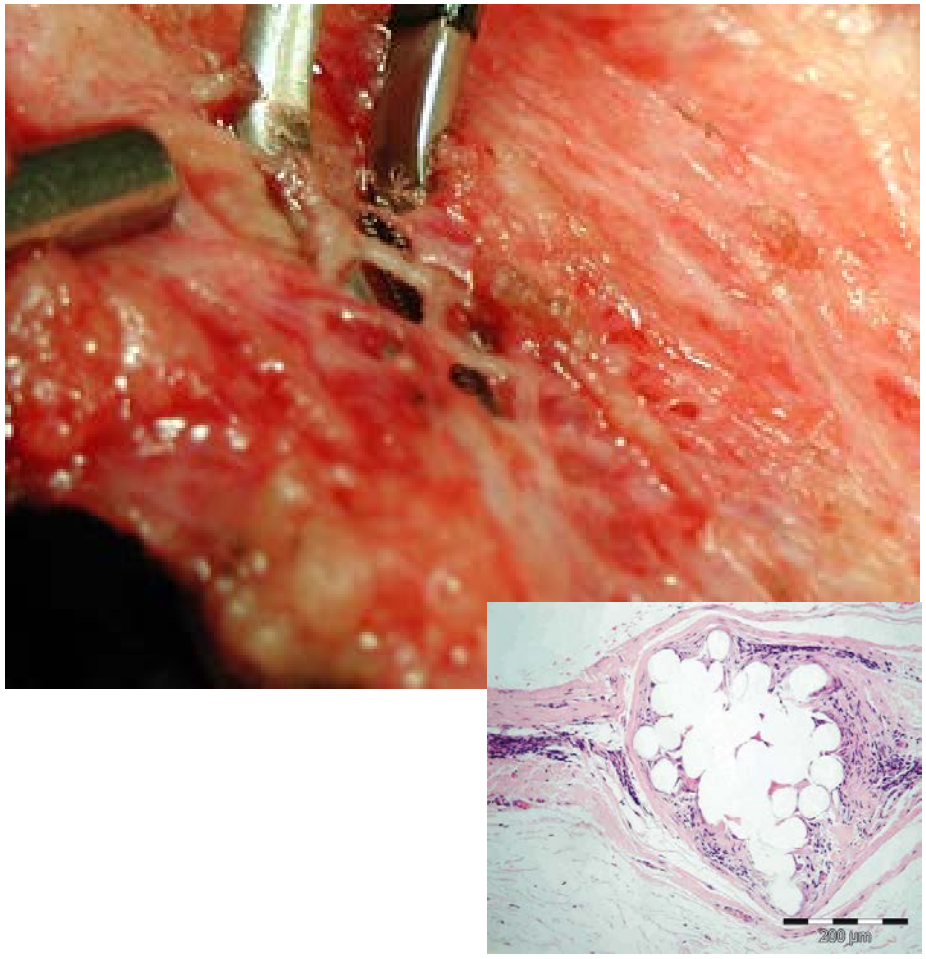
Klosterhalfen et al Br J Surg 2002

Textile structure with pores: tissue integration instead of fixation

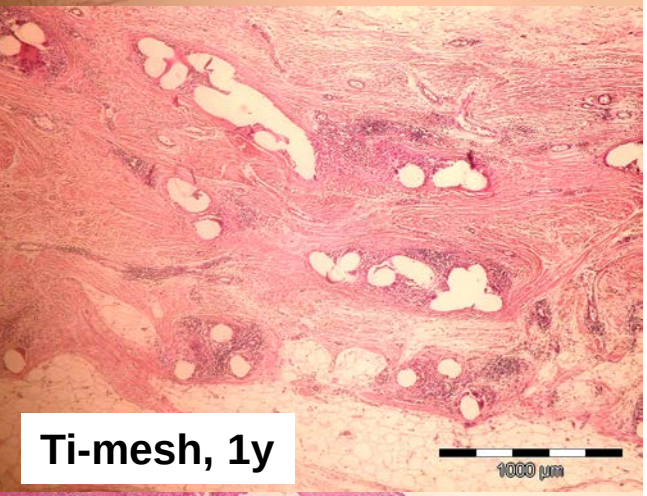
1 week

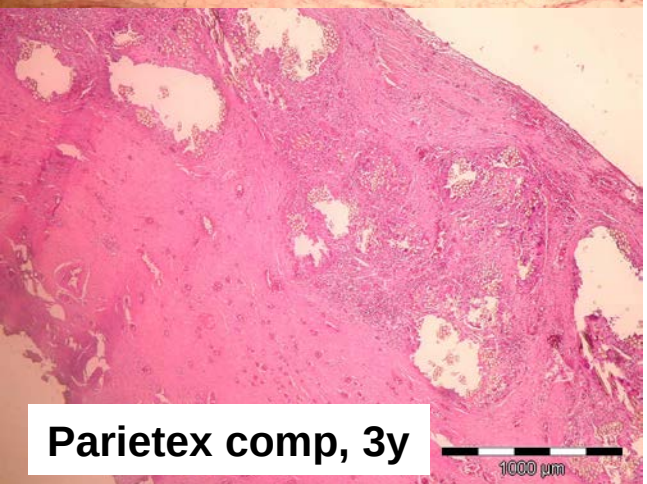


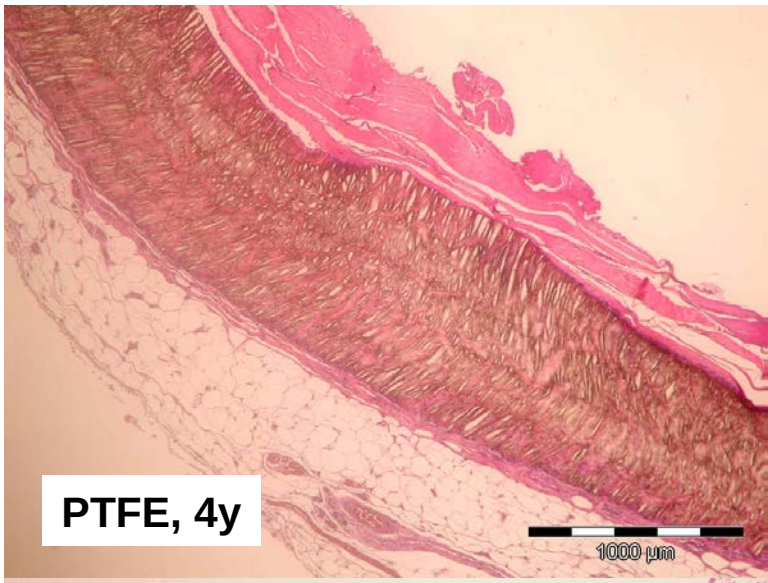
1 year



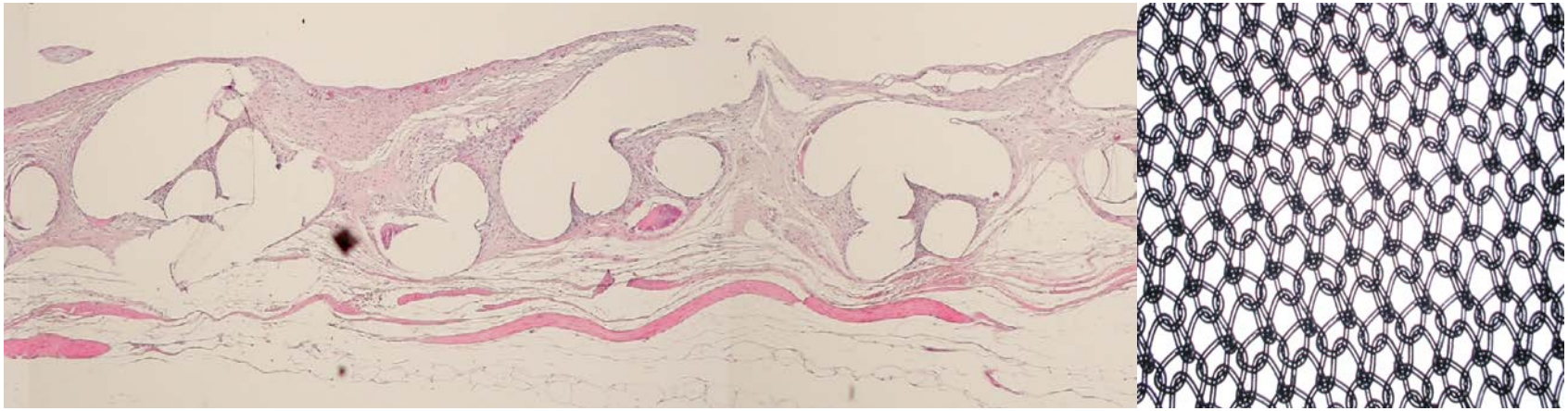
Explanted meshes



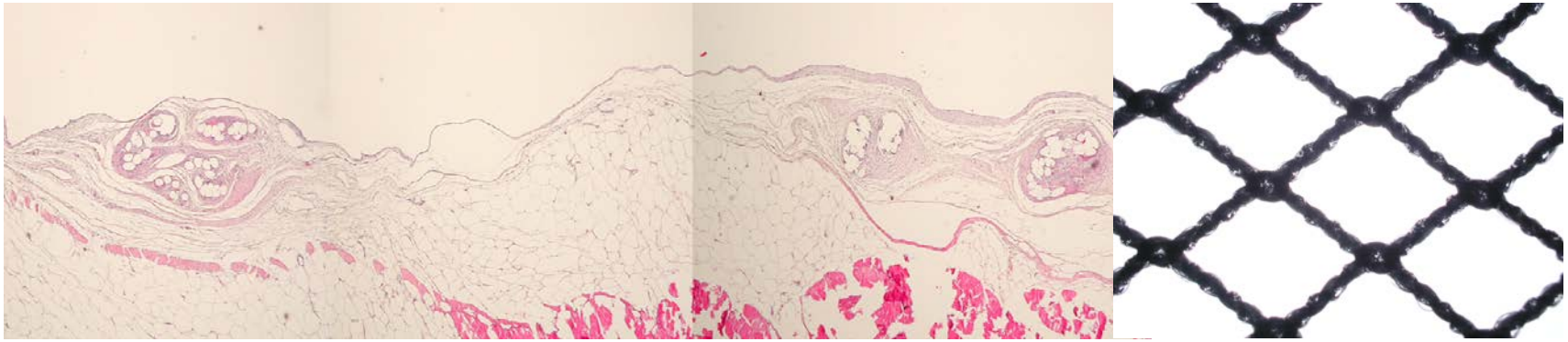




The pores and „bridging“

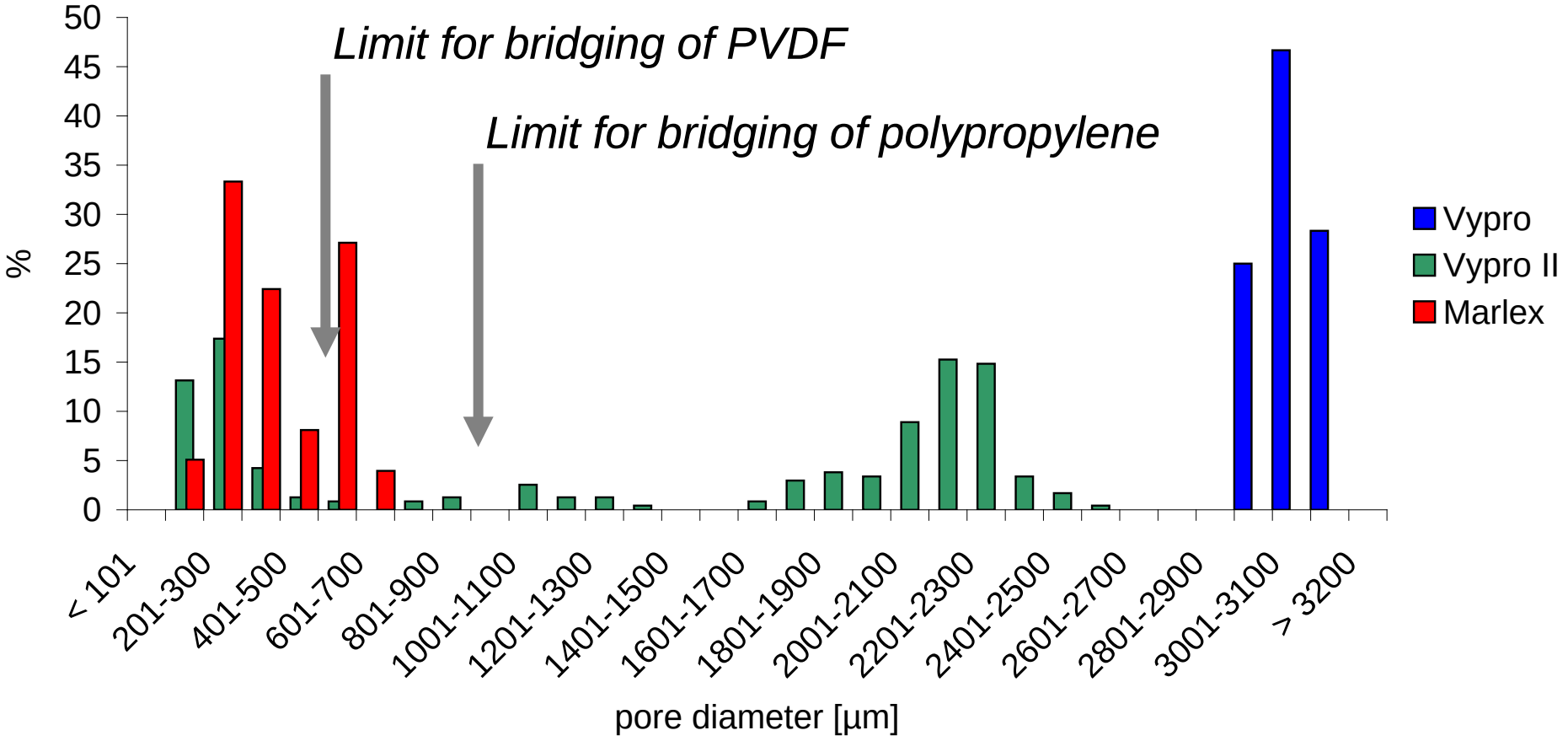


Pore < 600 µm: confluent scar plate („Bridging“)



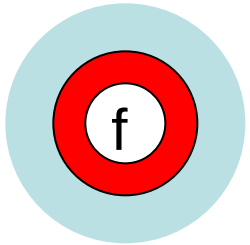
Pore > 3 mm: perifilamentary fibrosis („scar net“)

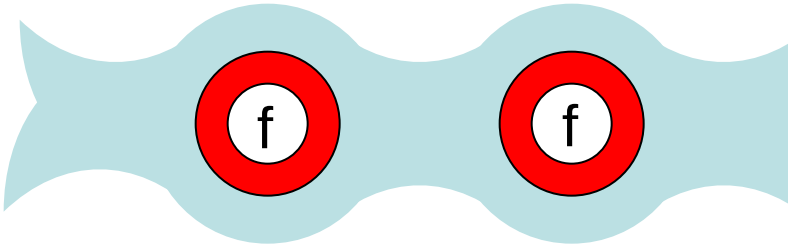
Histogram of mesh pore size

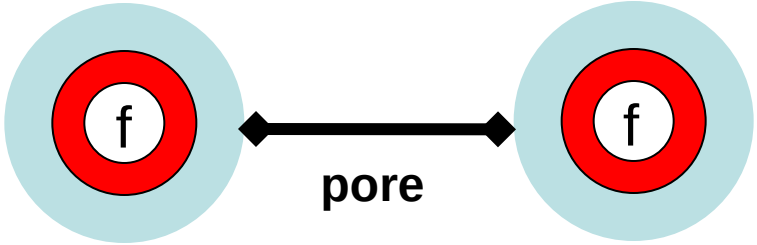


„Effective“ porosity considers foreign body granloma

foreign body granuloma



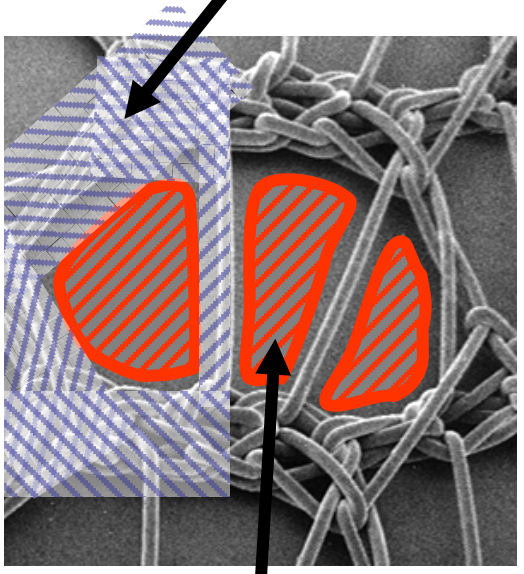




Minimum distance to prevent bridging:

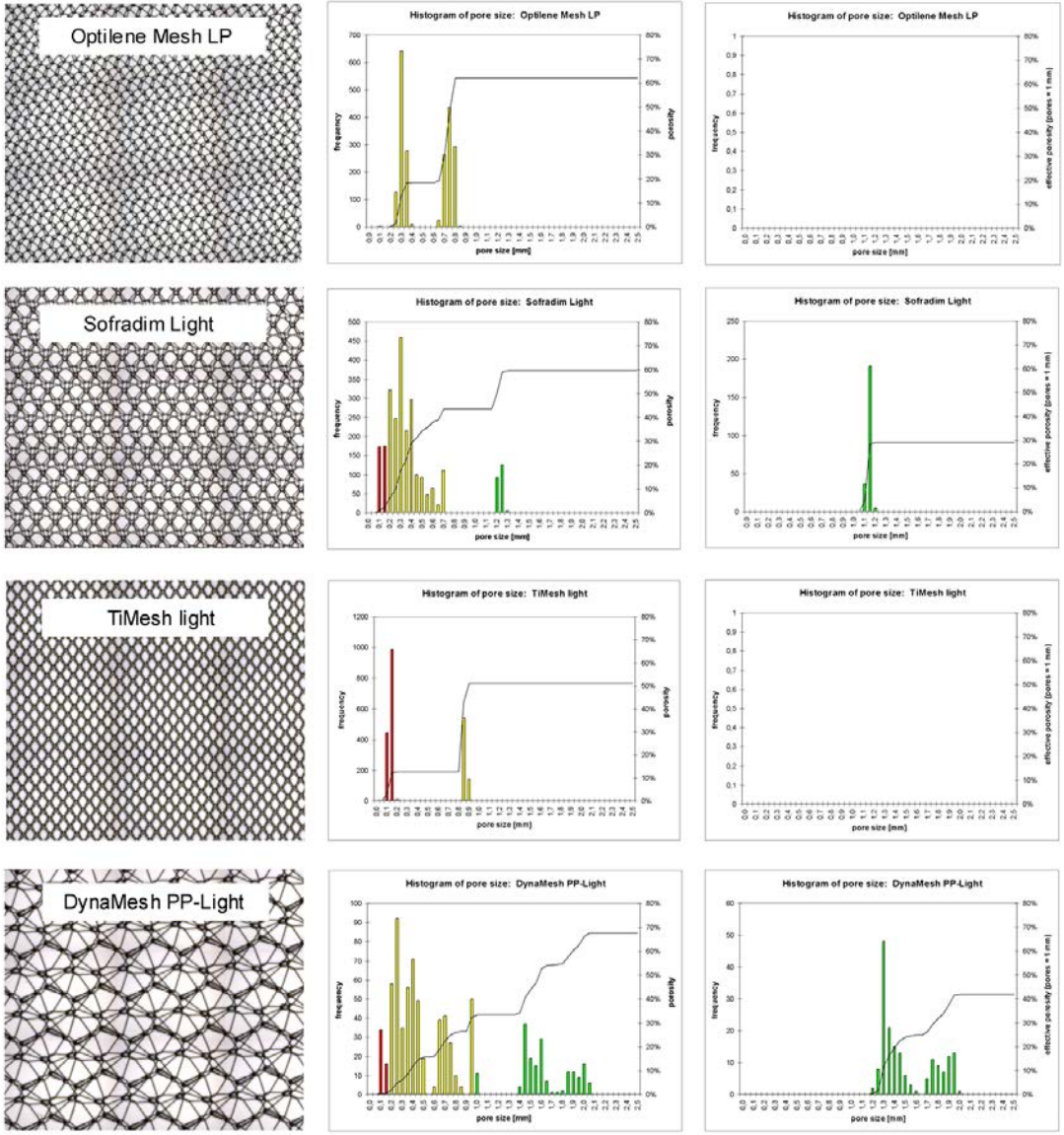
Polypropylene PP	1000 µm
Polyvinylidenfluorid PVDF	600 µm

granuloma

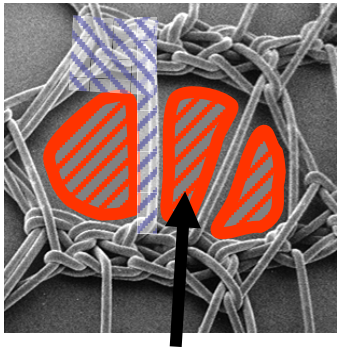


„recovery area“
= „effective“ porosity

"Effective" porosity of meshes, considering pore geometry



No effective porosity



No effective porosity

colour image

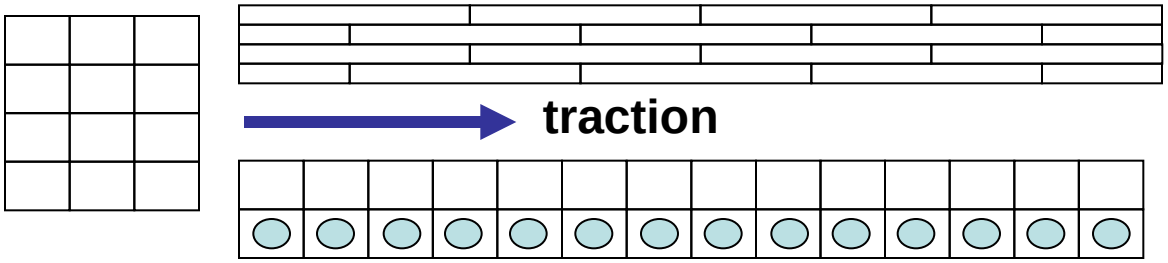
Histogram of pore size

Pores >1000 µm in all directions

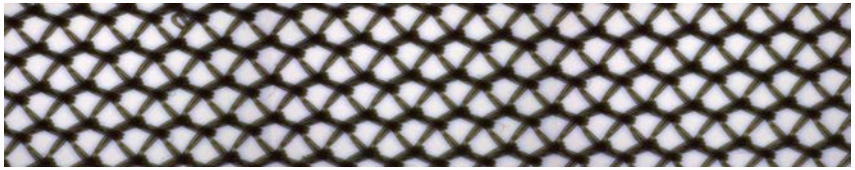
J Biomed Mater Res B Appl Biomater. 2007 May 11

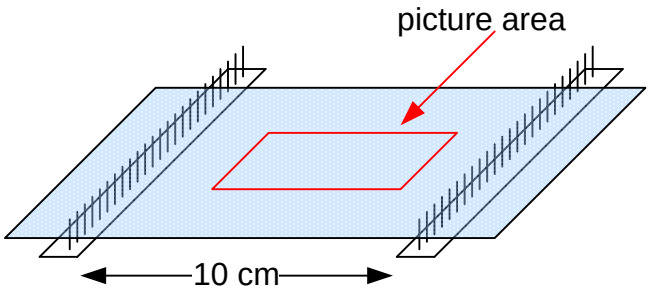
Deformation of pores under stress with consecutive reduction of „effective“ porosity

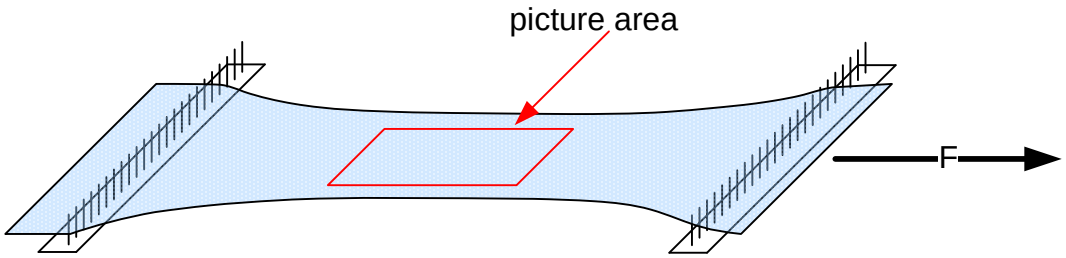
Slim pore: no „effective“ porosity



Preserved tall pore: „effective“ porosity



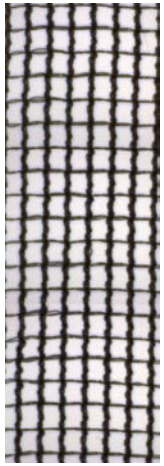




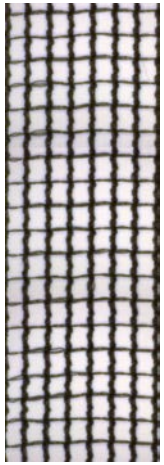
Stable structure under strain ?

DynaMesh SIS

probe dimensions:10 cm x 1,1 cm
picture size: 30,3 mm x 11,1 mm



force: 0,00 N

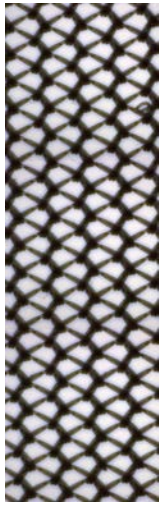


force: 9,81 N

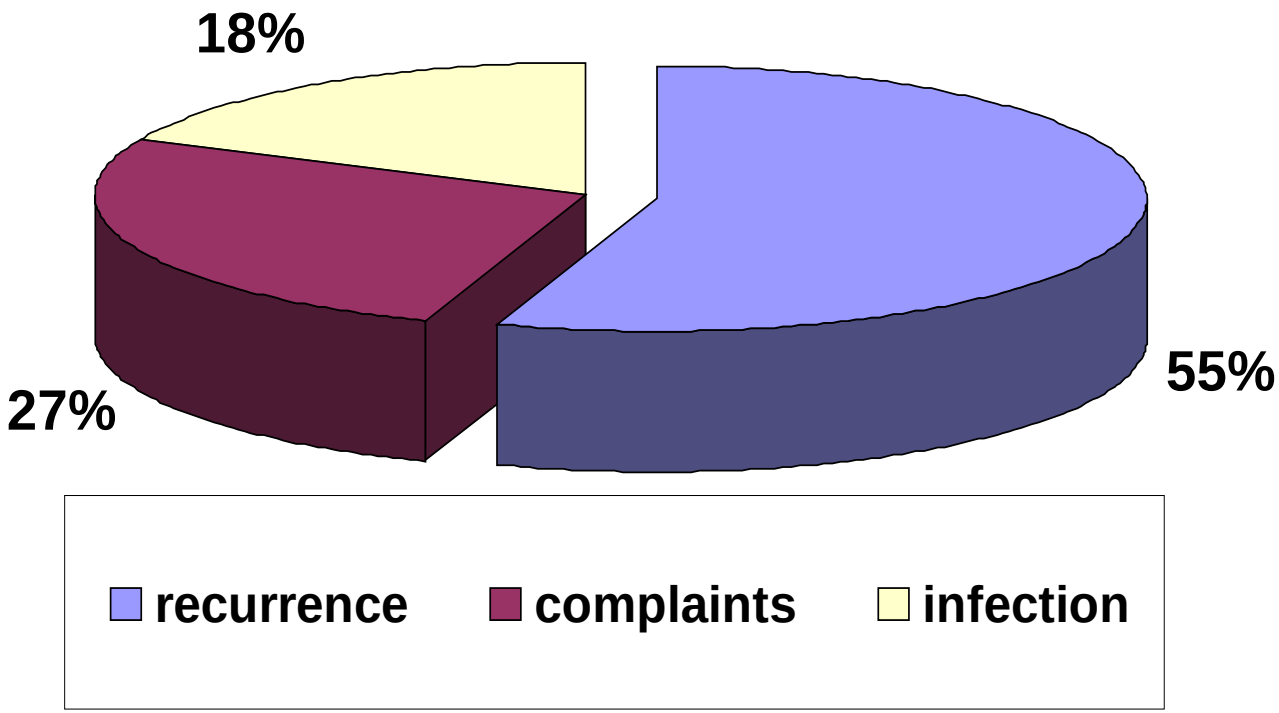
force: 19,62 N

Prolene

probe dimensions:10 cm x 1,1 cm
picture size: 30,3 mm x 11,1 mm



Clinical problems leading to removal of mesh material



347 explanted meshes for clinical problems

Prof. Klosterhalfen, Düren, Germany

Shrinkage

WORLD Journal of SURGERY

Relationship Between Tissue Ingrowth and Mesh Contraction

Rodrigo Gonzalez, M.D.,[1] Kim Fugate,[1] David McClusky III, M.D.,[1] E. Matt Ritter, M.D.,[1] Andrew Lederman, M.D.,[1] Dirk Dillehay, Ph.D.,[2] C. Daniel Smith, M.D.,[1] Bruce J. Ramshaw, M.D.[3]

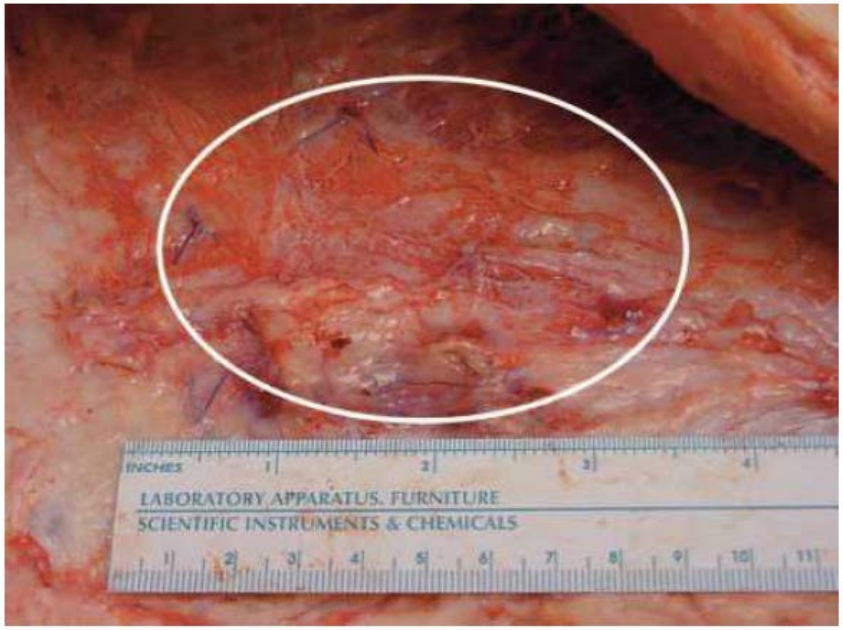


Fig. 3. All mesh prostheses in the study underwent contraction between 5% and 65% of their original size. Polyester mesh underwent less contraction than polypropylene mesh.

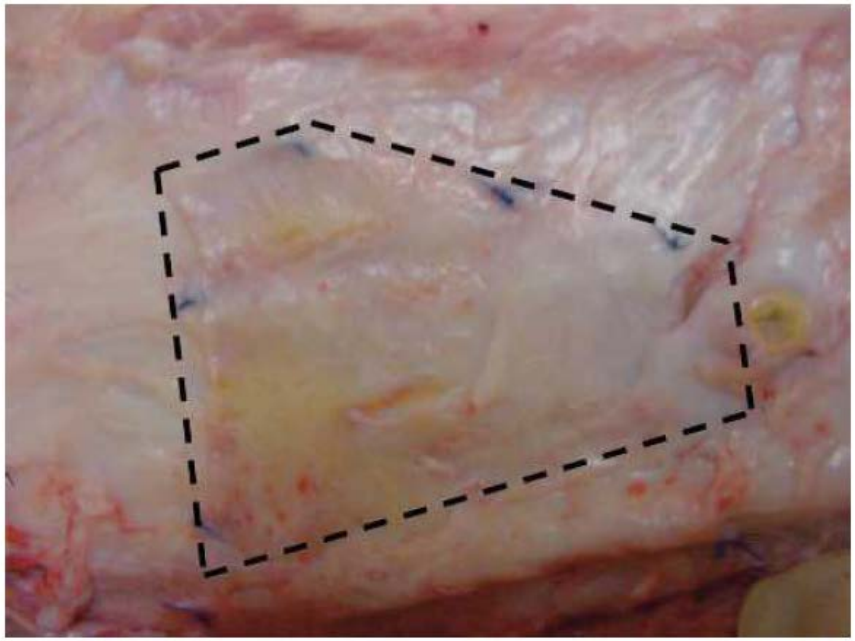
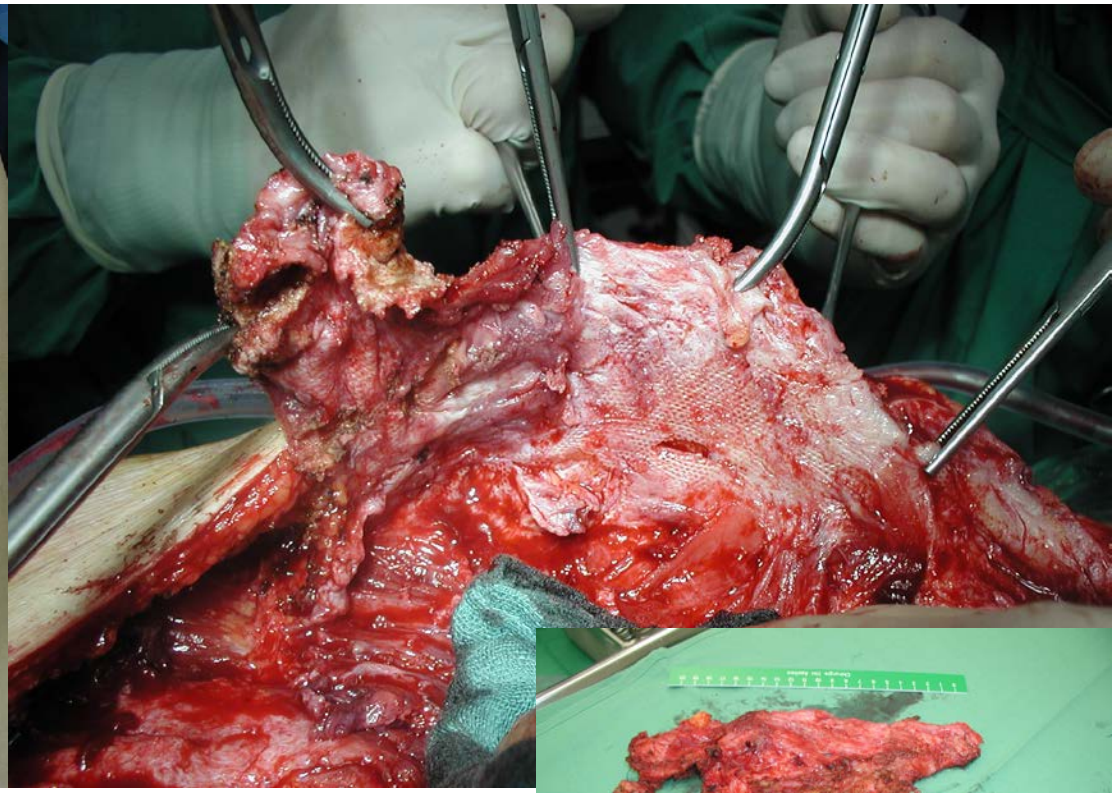


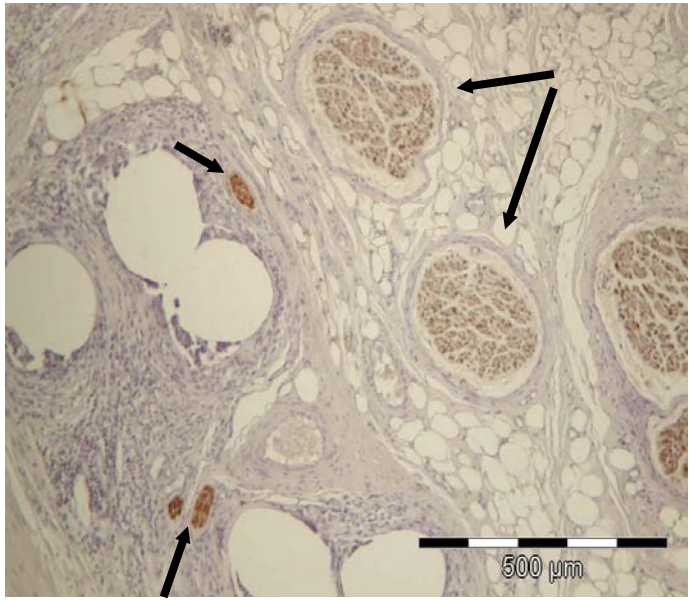
Fig. 4. Mesh that underwent the most contraction had detached from the fixation points.

Chronic fistula to an onlay PP-mesh



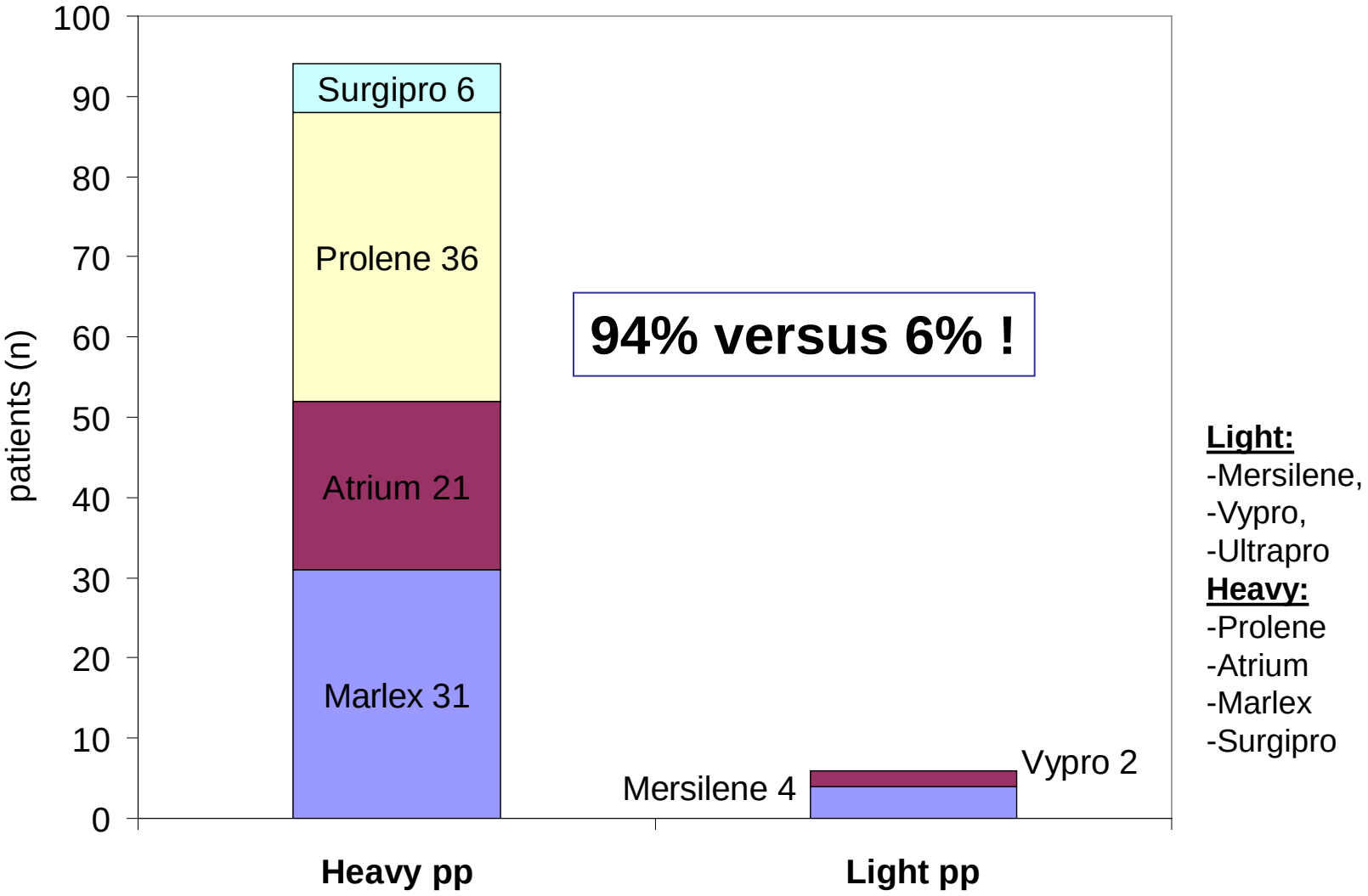
Mesh explantation and suture repair

Mesh and chronic pain



Small pore heavy weight PP-mesh, explantiert wegen Schmerzen (S 100)

Explantation of hernia meshes for chronic pain

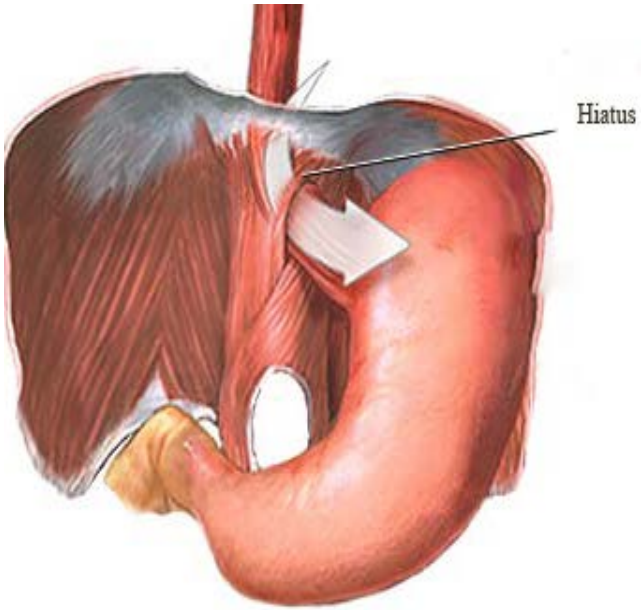


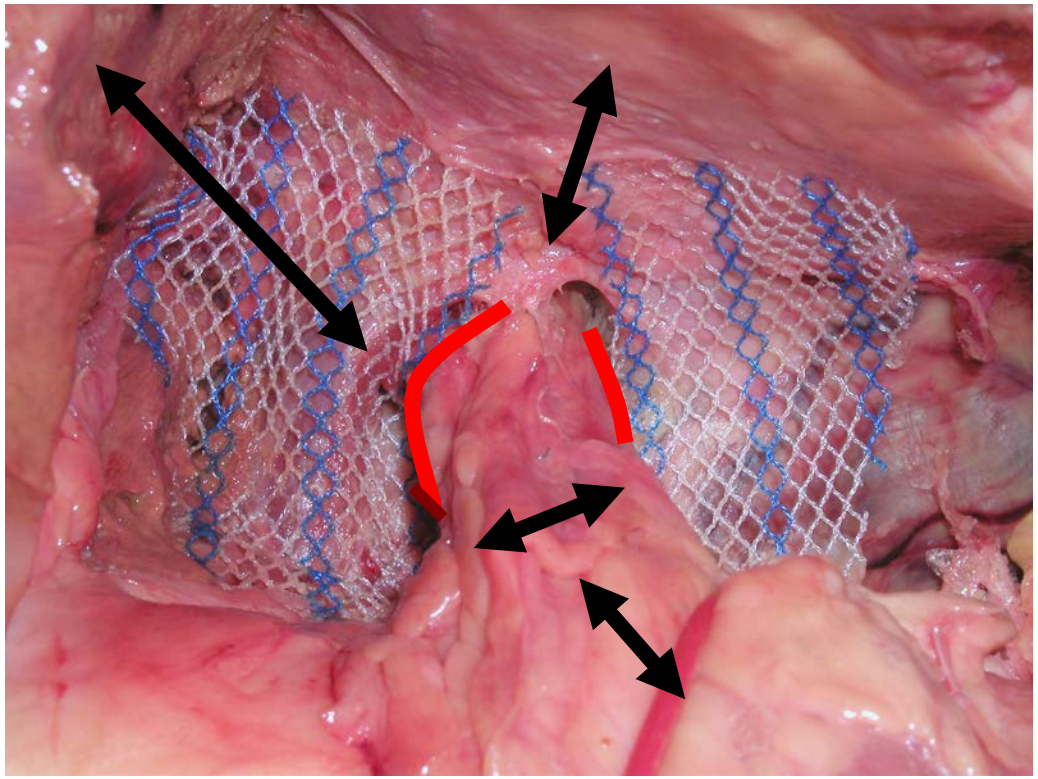
326 human explanted meshes (100 for pain)

Reduction of mesh related complications improving ….

- stretchability
- strength
- amount of material
- pore size
- filament geometry
- polymer
- surface
- tissue response by coating with ?)

Therapy of reflux esophagitis with mesh – risk for erosion and migration





mobility

stiff scar

Mesh at the pelvic floor

Polypropylene mesh

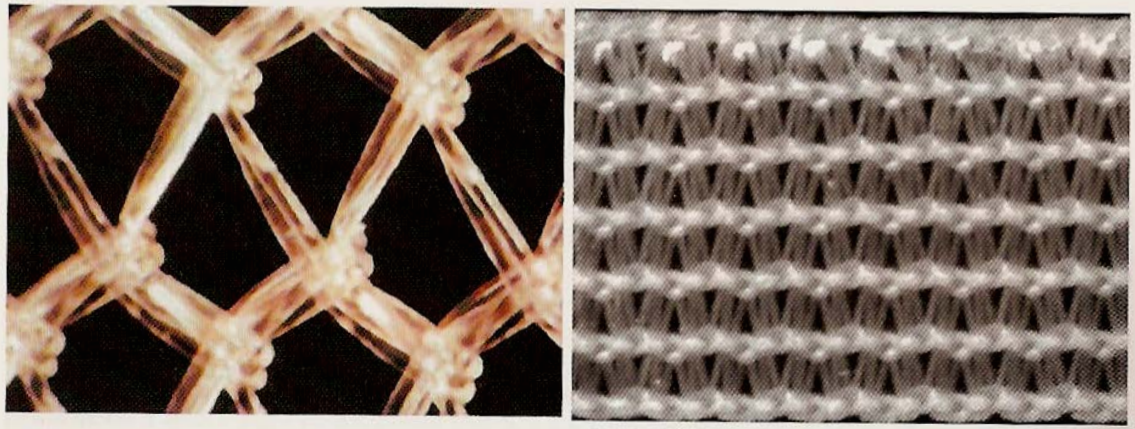
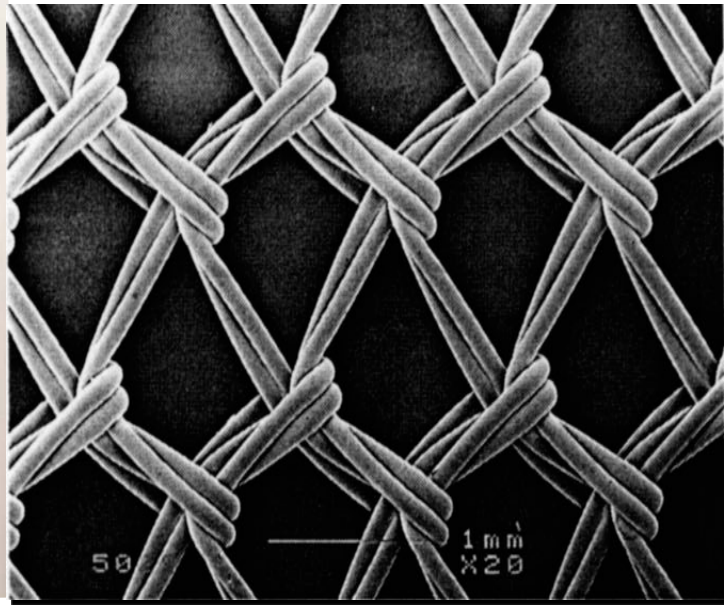


Fig 4-09 (Above left) Monofilament tape. The monofilaments are 100-150 microns thick. The spaces are relatively large. The diamond-shape allows the tape to be stretched into thin string which may transect the urethra.



Tape **Hernia**

PE Papa Petros: The female pelvic floor. Springer Medizin-Verlag Heidelberg, 2007, ISBN 978-3-540-33663-1

040809:

Thomas, Henry , 10.12.1970

Mesh: Prolene

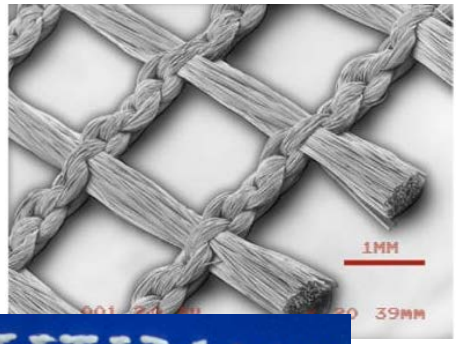
Implanted for 24 month

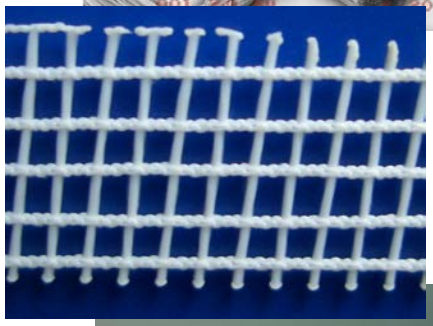
Pain: yes

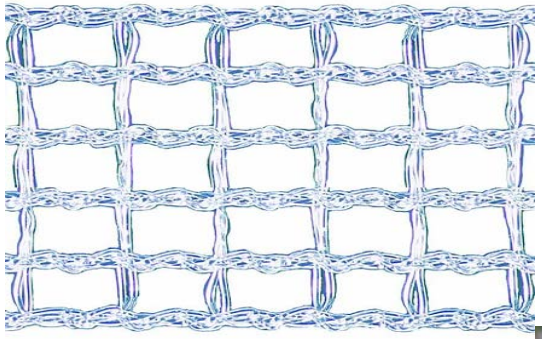
Recurrences: several

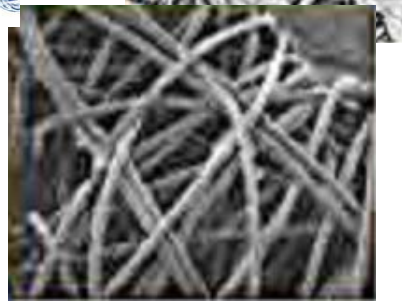
sling

Incontinence: tapes and slings

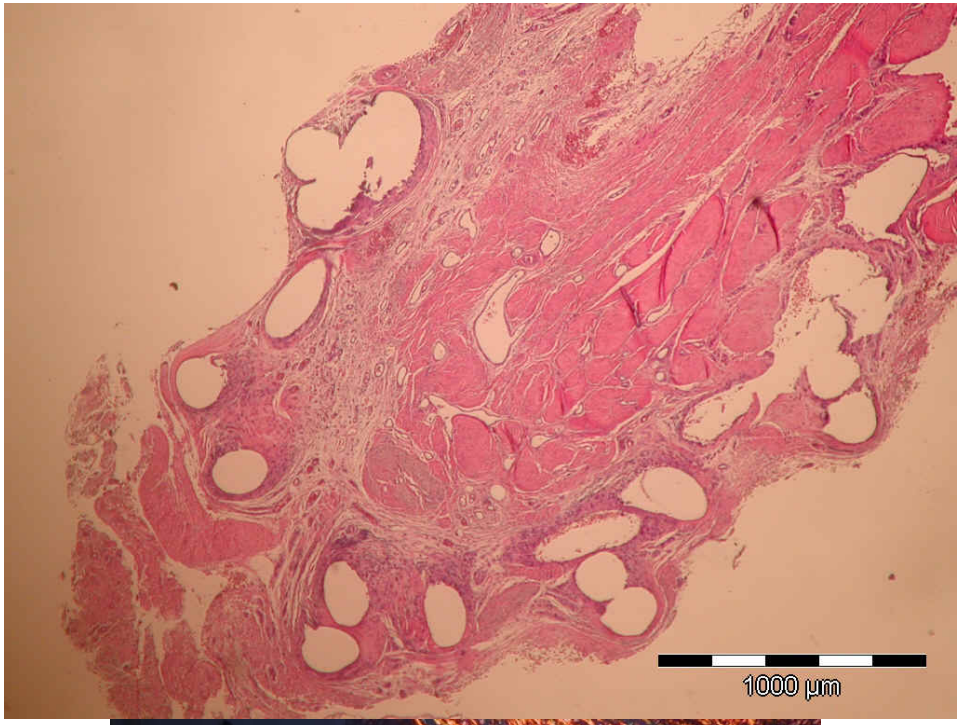


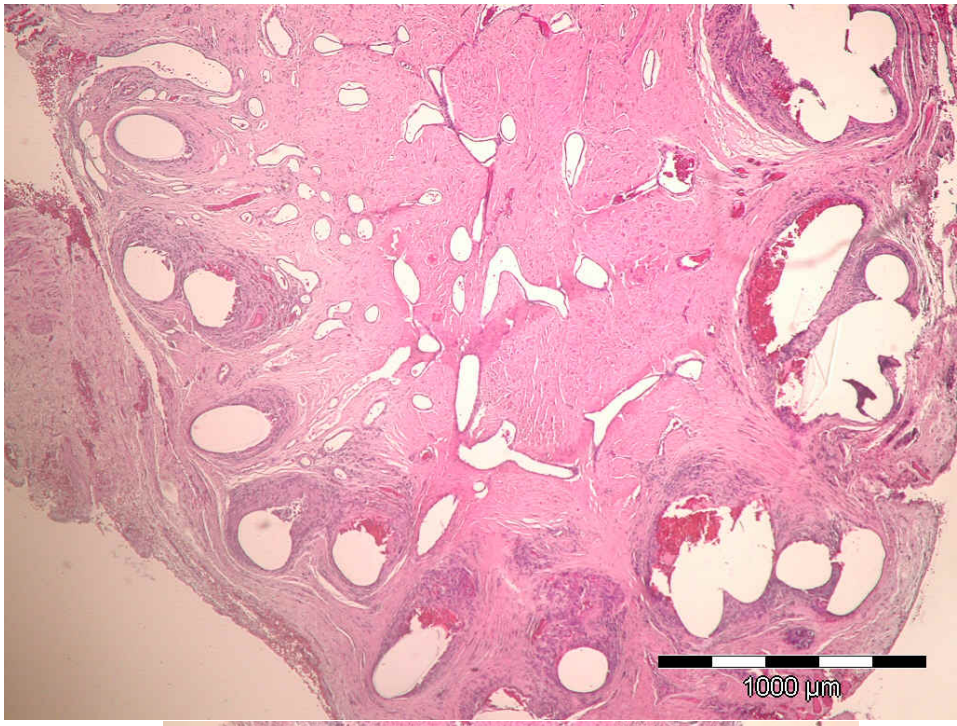


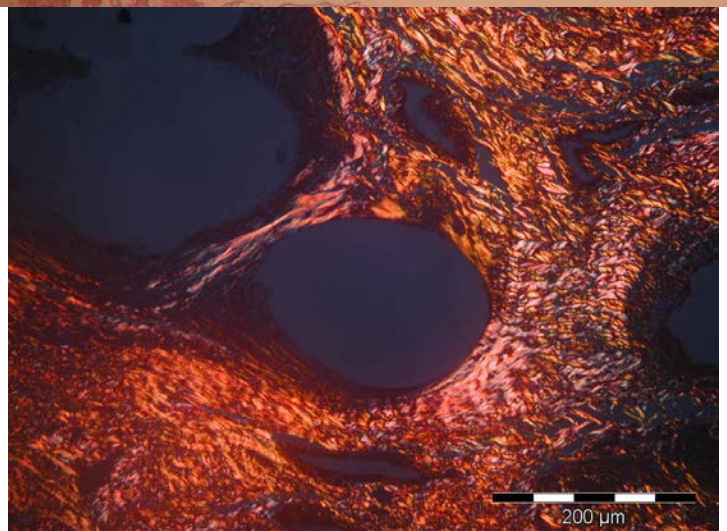




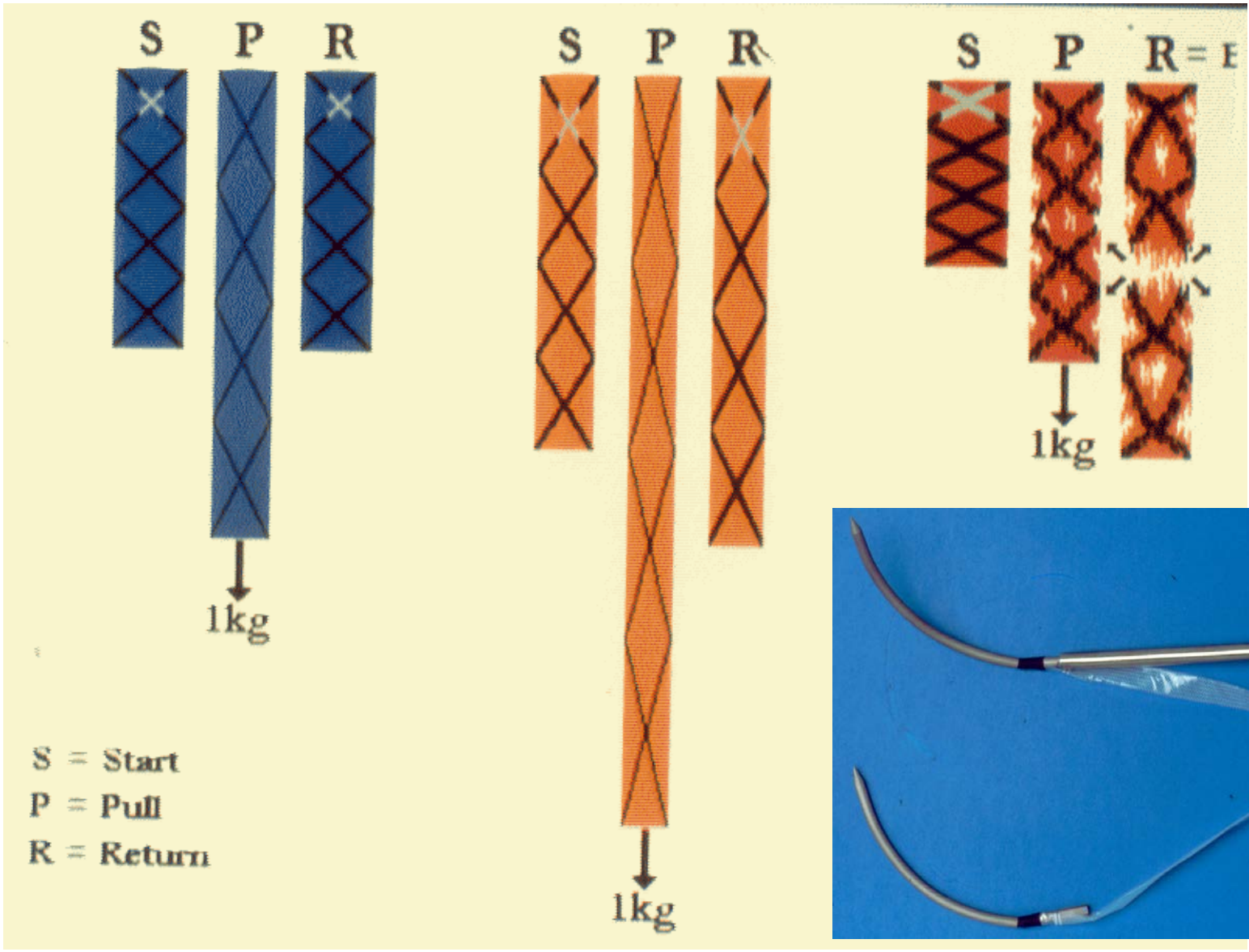
Roll in of the tape







Different strength of various tapes

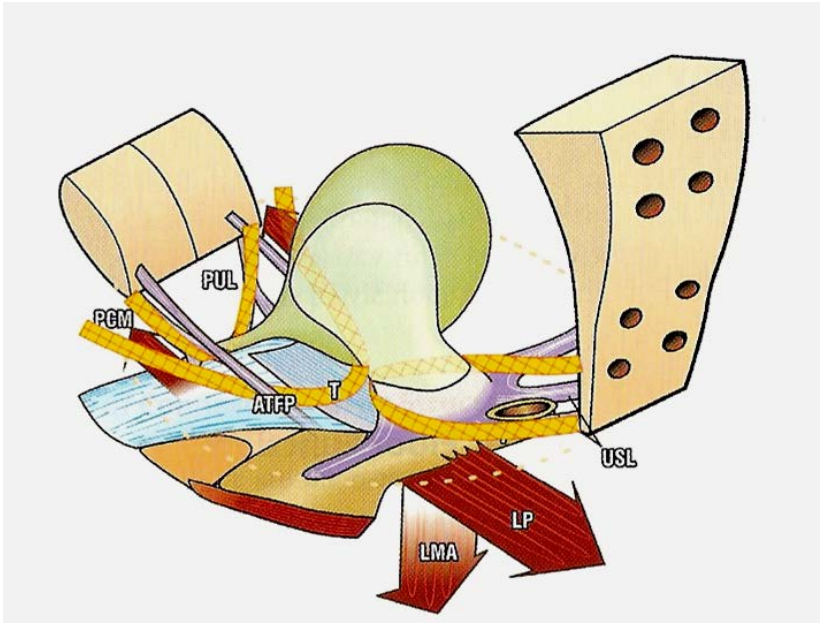


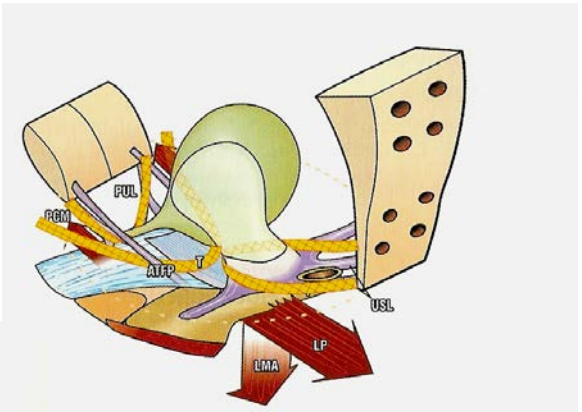
Dietz HP, Vancaillie P, Svehla M, Walsh W, Steensma AB, Vancaillie TG. *Pelvic Floor Unit, Royal Hospital for Women and Orthopaedic Research Lab., Prince of Wales Hospital*

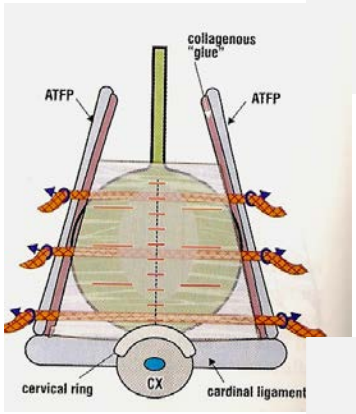
"Mechanical properties of implant materials used in incontinence surgery"

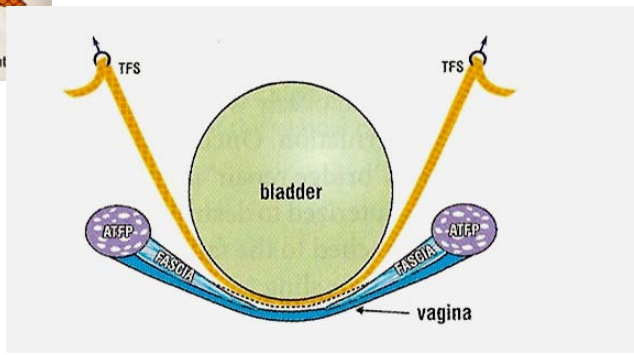
Material	Mean Stiffness (N/mm)	Mean Peak Load (N)
Nylon 66	6.83 (StD .28)	422.0 (StD 28)
IVS	1.58 (StD.31)	46.2 (StD 4.2)
TVT	0.23 (StD .05)	68.1 (StD 25.8)
Gore-Tex Soft Tissue Patch	2.68 (StD.24)	84.1 (StD 2.2)
Gore-Tex Mycro Mesh	2.61 (StD.11)	71.3 (StD 8.3)
Mersilene	1.17 (StD .14)	50.3 (StD 6.3)
Prolene	0.53 (StD .06)	56.4 (StD 5.9)

Textile device at the pelvic floor: flat mesh or tape ?



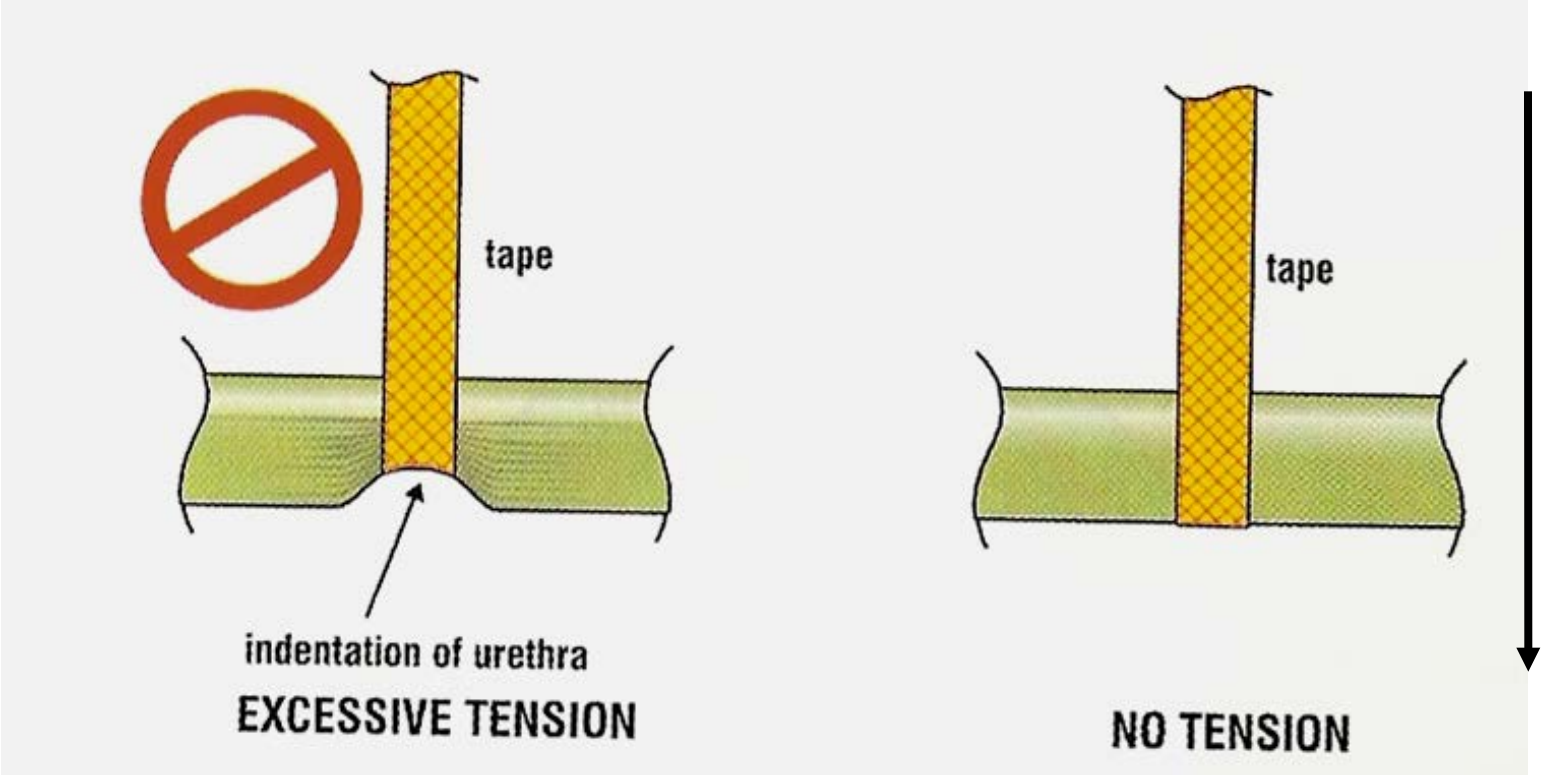






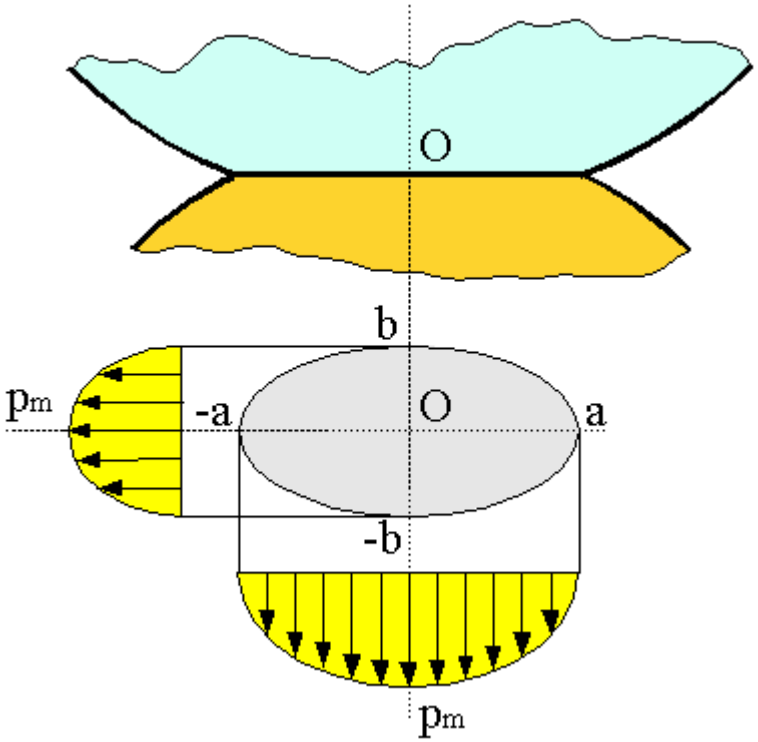
PE Papa Petros: The female pelvic floor. Springer Medizin-Verlag Heidelberg, 2007, ISBN 978-3-540-33663-1

Tension free and tape, is it possible ?

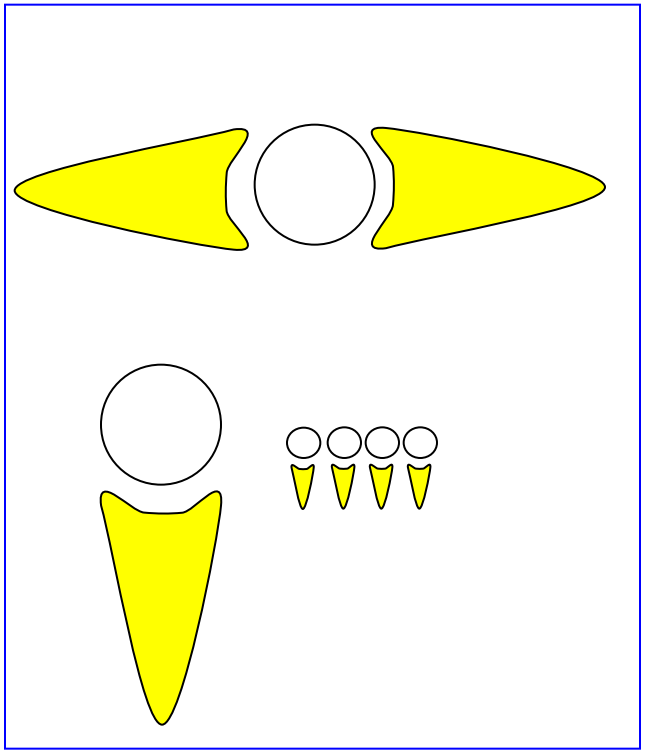


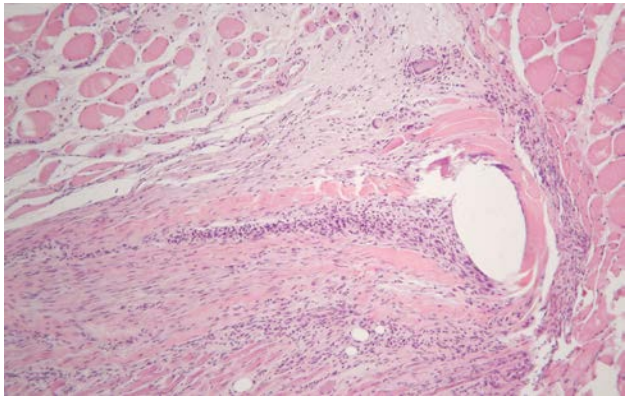
PE Papa Petros: The female pelvic floor. Springer Medizin-Verlag Heidelberg, 2007, ISBN 978-3-540-33663-1

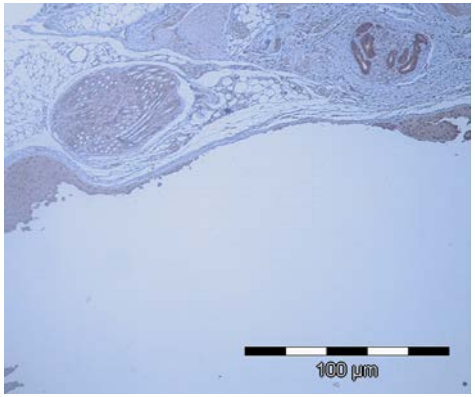
Tension to the fibre

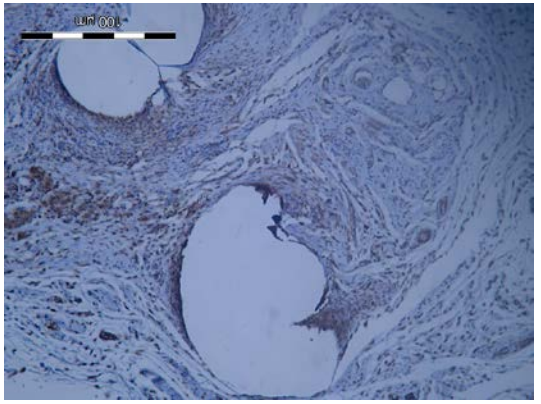


Comet tail necrosis

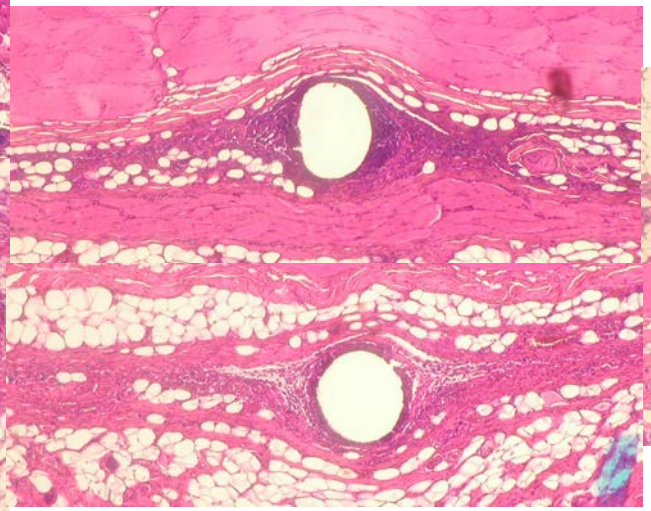


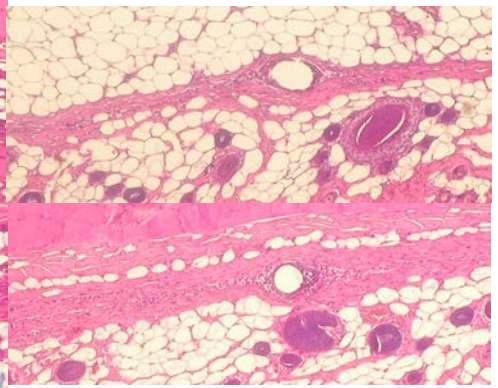






Comet tail as consequence of disturbed tissue archtitecture





5-7 fold
FD 500 µm

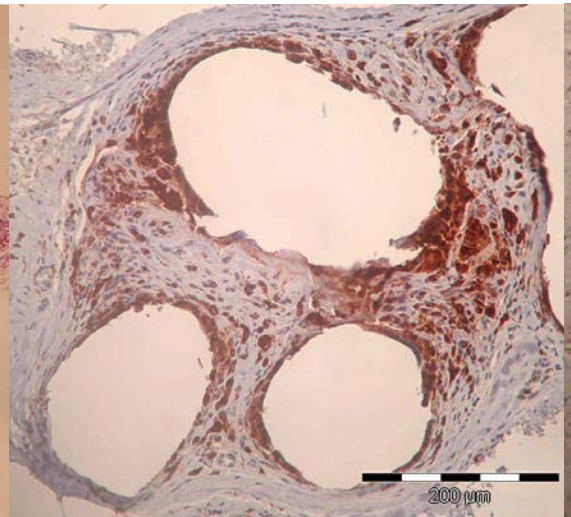
2-3 fold
FD 260 µm

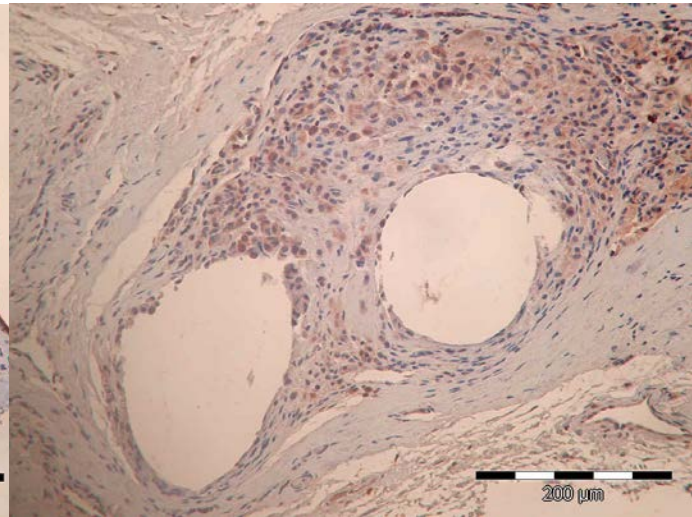
1 fold
FD 85 µm

(retarded) complications

- Obstruction by mesh shrinkage
- Infection
- migration and erosion, fistula formation
- pain

Cd 68 **MMP-2**





Erosion silicone

TRANS-OBTURATOR TAPE (T.O.T.®) FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE : A MULTICENTRIC PROSPECTIVE STUDY

Boccon Gibod et al.

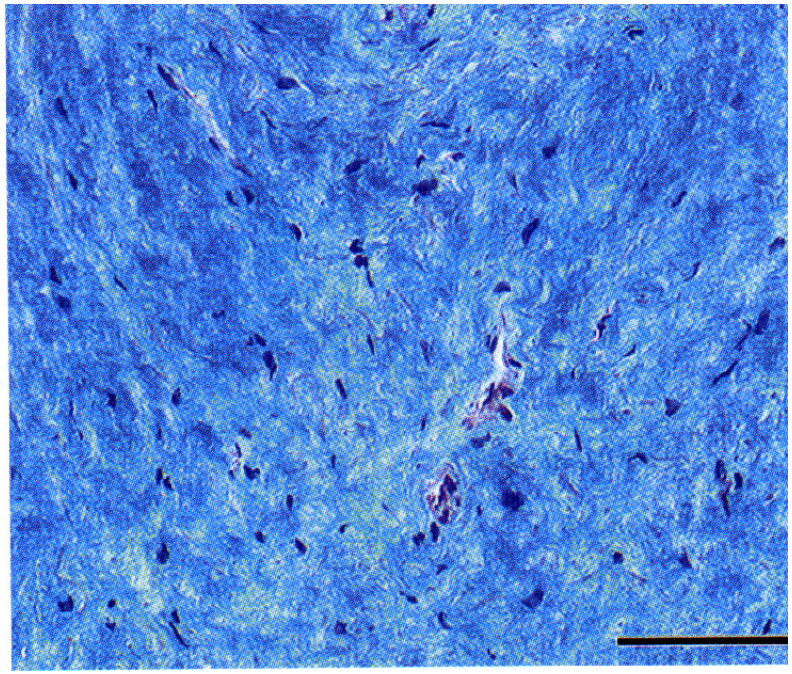
The rate of vaginal extrusion observed with Uratape® (5.6%) is certainly due to the silicon part under the urethra. With Obtape® (100% polypropylene) this rate (1.9%) decreased dramatically, and is in some cases related to a perforation of the sulcus of the vagina. Nevertheless, this rate is comparable to what has been already published with other polypropylene tapes.

Complications of silicone sling insertion for stress urinary incontinence.

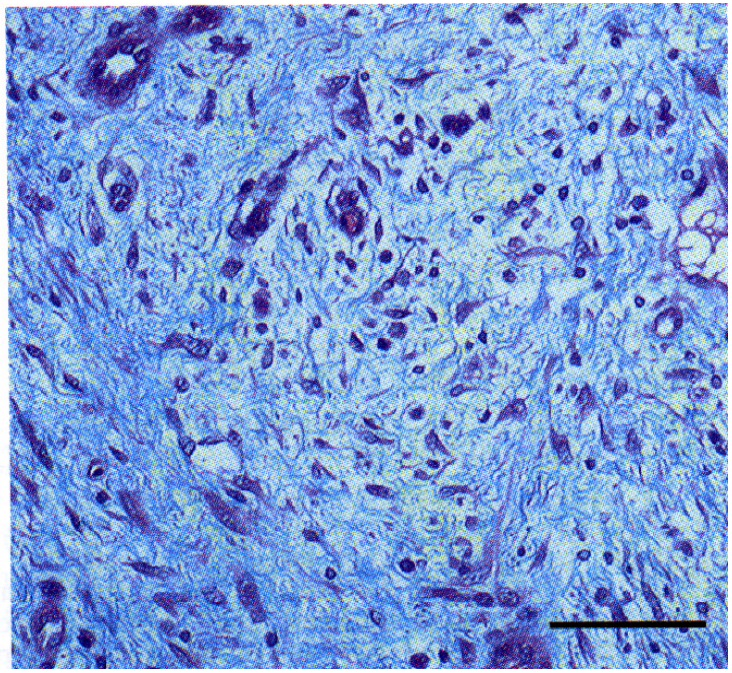
Duckett JR, Constantine G. Department of Obstetrics and Gynaecology, Good Hope Hospital, Sutton Coldfield, West Midlands, United Kingdom.

However, after 7 slings were inserted the study was terminated due to a high complication rate related to erosion and sinus formation in 5 slings which were removed. Complications developed immediately or up to 11 months after sling insertion. Continence was maintained in 4 of the 5 women after the slings were removed. CONCLUSIONS: **Silicone is an inappropriate material** for suburethral sling placement when used as described in our cases, caution should be exercised when placing silicone slings at this site.

2 years after TVT operation



Prolene



Mersilene

Falconer et al., Int. Urogyn. J., 2001

Erosion of woven polyester pubovaginal sling.

Kobashi KC, Dmochowski R, Mee SL, Mostwin J, Nitti VW, Zimmern PE, Leach GE.

Tower Urology Institute for Continence, Cedars-Sinai Medical Center, Los Angeles, California, USA

CONCLUSIONS: Woven polyester slings treated with pressure injected bovine collagen are prone to erosion. Although the ProteGen sling was recalled in January 1999, patients who have had the sling placed must be followed closely.

Monofilament vs. multifilament

10 CASES OF INFECTIONS WITH SUB-URETHRAL MULTIFILAMENT POLYPROPYLENE MESH SLING REQUIRING REMOVAL OF THE SLING

Baghi A[1], Trastour C[1], Benizri E[2], Bongain A[1] *[1]Department of Gynecology and Obstetrics, [1]Urologic Center, Belvedere Clinic , Nice*

Concluding message

It seems that multifilament mesh is more likely to be infected and requires sling removal, contrary to rare infections with monofilament mesh in literature. It is important to report all specificities of such prostheses which are more and more used in vaginal surgery, especially in prolapse cure procedures.

Erosion, defective healing and extrusion after tension-free urethropexy for the treatment of stress urinary incontinence.

Glavind K, Sander P Department of Obstetrics and Gynecology, Aalborg Sygehus Nord, 9000, Aalborg, Denmark. glavind@dadlnet.dk

A case-control study was performed in two departments performing tension-free urethropexy for the treatment of stress urinary incontinence. During a period of 4.5 years, 127 cases of tension-free vaginal tape operations (TVT) and 42 cases of intravaginal slingplasty (IVS) were performed. In the TVT group one case of urethral erosion was observed, but in the IVS group six cases of defective healing, erosion or extrusion were observed. It is considered that the complications might be due to the multifilamentous nature of the IVS tape in contrast to the monofilamentous nature of the TVT tape.

Requirements for textile devices

- Elasticity ?
- Stiffness ?
- Strength ?
- Stable structure under strain?
- Fibrosis?
- Inflammation?
- Tissue integration?
- Migration, cell turnover

- No multifilament?
- No silicone?
- No polyester?

mesh ?
or
Tape ?

Evolution of Meshes

- **1. Generation:** Usher 1959 introduced PP and Polyester meshes in dogs → but meshoma, pain, seroma
- **2. Generation:** Light-weight meshes with reduced amount, large pores, Vypro with multifile PP (Aachen 1993) → but abdominal adhesions, stability of the textile structure without absorbable additive ? Monofile construction ?
- **3. Generation:** Mesh with further reduced surface and increased effective porosity in form stable, monofilament structures of PVDF with least inflammatory activity
  → but recurrence, migration ?
- **4. Generation:** bioactive mesh modifying tissue reaction and wound healing by coating with ? Glucamesh? Gentamicin? ____?

Requirements for textile structures at the pelvic floor

Large pore (> 1 mm, no Film), moderate elasticity (< 10%), high form stability under strain to avoid roll in !

Little tensile strength (> 2 N/cm)

Width of = 1 cm, since smaller tapes cut through easier

Little tension to the fibres

Little remodelling at the fibre surface

Little inflammation, little fibrosis = little shrinkage

No sharp edges

Permanent polymer with standardized properties (no Polyester, no silicone, no biological)

Thank you very much for your kind attention

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